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**In the Supreme Court of the United States**

**OCTOBER TERM 1957**

**No. 27**

**MARION B. FOLSOM, Secretary of Health,  
Education and Welfare,  
Petitioner**

**-VS-**

**FLORIDA CITRUS EXCHANGE, et al,  
and  
FRANK R. SCHELL,  
Respondents.**

**BRIEF OF RESPONDENT FRANK R. SCHELL**

• • • •

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FRANK R. SCHELL**

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of Counsel for Respondent**

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### ERRATA IN RECORD

R. 87: Re Experiment 9, first par., line 2, "dilation" should read "dilution".

R. 141, 2nd complete par., line 11: "710/0", should read "7/100".

R. 146, 4th par., reads:

"On January 19, he said the administration would open formal hearings *on the subject of whether orange color with coal-tar dyes.*";

whereas the same should read (see correct quotation of omitted language at R. 147):

"On January 19, he said, the administration would open formal hearings *on the subject of whether orange growers would be allowed to continue tinting their fruits orange color with coal-tar dyes.*"  
(Emphasis supplied).

Regrettably, neither the record herein, or in the Court below, shows the page where F&DA's Ex. 4 (Hearing of January 19, 1954) was formally offered in evidence (at p. 37 of the Transcript of Record of Hearing held on January 19, 1954). Ex. 4 was offered for identification at R. 205, and at R. 240 there appears the Reporter's note that it was offered by the Government on that date. Where required by Rule 40 (2) we have used R. 205 as the page reference.

### Abbreviations Used

In this brief the following abbreviations and designations have been used:

"Secretary" refers to Hon. Marion B. Folsom, Secretary of Department of Health, Education and Welfare and his successor in office..

"Respondent" refers to Frank R. Schell.

"R. ...." refers to pages of Transcript of Record in this Court.

"Ap. ...." refers to pages of Appendix to this brief.

"U.S.D.A." refers to Federal Dept. of Agriculture.

"F&DA" refers to Federal Food and Drug Administration.

"The Act" refers to 1938 Food, Drug and Cosmetic Act.

"The 1906 Act" refers to 1906 Food and Drug Act.

"Color Added" refers to process for coloring oranges with coal-tar color.

"Red 32", or similar words, refers to the coal-tar color FD&C Red No. 32 or other certified coal-tar colors.

"Dunn, \_\_\_\_\_" refers to pages in work titled "Federal Food, Drug and Cosmetic Act." (1938) by Charles Wesley Dunn, being a compilation of official records of the Congress re food and drug legislation over the years 1933 to 1938, both inclusive.

"Ppm" refers to ratio of parts of color per million parts of food colored therewith.

"Coal-tar Color Regulations" refers to F&DA Regulations re certified coal-tar colors, promulgated in 1940 and titled "Coal-tar Color Regulations, S.R.A., FDC 3, "(21 C.F.R. 135, part 9)."

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**Brief of Respondent Frank R. Schell**

**STATEMENT OF THE CASE**

We are unable to accept the statement set forth on pages 5-14 of Petitioner's Brief and under various subheads will set forth what we conceive to be the factual matters to be considered by the Court in the disposition of this cause.

These matters will be presented under subheads as follows:

- (1) The Artificial Coloring of Oranges and the Importance Thereof to the Citrus Industry.
- (2) History of Color-Added Process and Proceedings with regard thereto.
- (3) Statutes Involved.
- (4) The Tests Upon Which the Secretary Based the Order do not Justify or Substantiate the Order.
- (4)(a) New Legislation.



Following the material presented under the above subheads, we will present the issues and our arguments thereon under the subheads:

(5) Questions Presented.

(6) Argument

- (a) The issues in this case.
- (b) The language of the Act.
- (c) The legislative history of the Act.
- (d) Contemporaneous administrative construction of the Act.
- (e) F&DC Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.
- (f) The Circuit Court of Appeals of the Fifth Circuit correctly decided this cause.
- (g) Conclusions.

The fundamental facts in this case are that the Secretary of the Department of Health, Education and Welfare decertified certain coal-tar colors that are used in the Color Added process for coloring oranges.

The tests conducted by the Food and Drug Administration demonstrated that when these colors were fed to dogs in massive doses they produced adverse effects. The F&DA, however, admitted frankly that in the amounts used to color oranges there was no evidence whatever that such colors would or could produce any adverse effects.

The Secretary, however, takes the position that the Food, Drug and Cosmetics Act of 1938, hereafter referred to as the 1938 Act, does not authorize him to restrict the use of such colors to a particular purpose or limit the amount that may be used for such purpose

and that having established that the colors are toxic in the smallest degree he has no alternative except to decertify such colors and make their use for any purpose and in any amount unlawful.

The fundamental issue of law in this case revolves around the word "harmless" as the same appears in Section 406 (b) of the 1938 Act.

The Secretary takes the arbitrary position that "harmless" as used in the 1938 Act must be construed in its *absolute* sense, that is, that before any color may be used to color oranges it must be *absolutely harmless* in any and all amounts.

We take the position that the word harmless as the same is used in the 1938 Act is to be construed in its *relative* sense, that is, that a color shall be certified by the Secretary if the same is harmless for the purpose for which it is intended and in the amounts used for such purpose.

Section 406 (b) of the 1938 Act mandatorily requires the Secretary to certify coal-tar colors that are "harmless and suitable for use in food" and it is our contention that the colors in controversy are harmless and suitable for use in coloring oranges, and the F&DA admits as much but refuses to certify such colors for such purpose.

The Circuit Court of Appeals held that under the facts in this case is was the duty of the Secretary to certify FD&C Red No. 32 (one of the colors in controversy) for use in coloring oranges.

From that judgment the Secretary seeks review by this Court.

## **THE ARTIFICIAL COLORING OF ORANGES AND THE IMPORTANCE THEREOF**

In explanation of what might otherwise be deemed

an unnecessary digression, we respectfully submit our conviction that a consideration of the issues in the instant case cannot be properly approached without an appreciation and consideration of the history of the coloring problems of the orange industry and what has been done in the past to solve them.

These problems stem from the fact that, unfortunately, no horticulturist has ever been able to make the exterior color of an orange conform to inner maturity as the orange ripens, and all varieties - early, mid-season and late - continue to attain their optimum color during the few months of cold weather, as did their ancestors along the shores of the Mediterranean.

U.S.D.A. succinctly and effectively stated the whole problem in its Yearbook for 1932 (pp. 134-137):

*"Some of the early Fall varieties of oranges and grapefruit ripen while the fruit is still green in color. Later varieties that mature in the Spring or Summer assume the color of full maturity during the winter while the fruit is still immature, but when warm weather occurs the rind may turn green again. Thus while the edible part of the fruit ripens, there is a 'regreening' of the rind. Grapefruit growing inside of densely foliated trees never develops full color, although some of the best flavored fruit is produced there. There is therefore no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale, and the price that it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."* (Emphasis ours.) (R. 122-123).

## **The Ethylene Gas Process For Coloring Citrus Fruit**

In the year 1923 Dr. Frank E. Denny, U.S.D.A. obtained and dedicated to the public Letters Patent of the United States No. 1,475,938, entitled "Method of Coloring Citrus Fruits," which process is generally known as the "ethylene gas process." This Patent's single claim recites:

"A new and useful method of coloring citrus fruits, consisting in bringing ethylene gas into contact with green citrus fruits, and maintaining that contact at a temperature as low as 55 degree F., and below 85 degree F."

The process was so successful that within a comparatively short space of time it was in use in practically every citrus packing house in the country.

While the ethylene gas process was an important aid to the development of the orange industry, nevertheless the process has its limitations and imperfections. Without expanding this subject, it may be said that the use of ethylene gas is far from a simple procedure, its proper application requiring experts in that field, otherwise the fruit may be weakened, resulting in an increase in "stem and rot" and other forms of decay. At best the fruit, depending on various factors, may have to remain in the coloring rooms for 36 to 96 hours. This time alone is a detrimental factor.

Further, it is impossible to secure a uniform coloration. As stated in the Yearbook of Agriculture for 1932, page 136:

"Experience has shown that few citrus crops react alike to the coloring process, since growing conditions have a marked influence on the rate of coloring. Variable weather conditions and variations in the condition of the fruit itself from time to



time prevent adoption of a standardized coloring procedure."

### **The Color-Added Process For Coloring Citrus Fruit**

These considerations, among other, prompted the development of what came to be known, in 1934, as the "Color Added" process (those words being the declaration of added color required to be stamped on the peel of oranges so colored).

The Color Added process constitutes merely an improvement on the prior coloration practices, the only variation requiring mention here being the use of a minute amount (4 parts of color per million parts of the whole orange) (R. 141, ~~in 1934~~) of an oil soluble, water insoluble, certified food color, with which the very thin ( $1/1000$  inch) outer layer of waxy and oily constituents of the peel are impregnated by spraying or pouring on, or immersing oranges in, the coloring solution, for a period of some three minutes

The food color used does not penetrate beyond the oil cells in the thin outer cuticle of the orange, and is physically incapable of entering and coloring the white portion of the peel or rag which are oil resistant and water absorbing.

### **Importance Of Color Added Process To Citrus Industry**

The use of the process is of vital importance to the industry - not only from a financial but also from a production viewpoint. This is well established by the following production figures for oranges, showing the production, in million of boxes, in California (where Color Added was not used commercially until 1957) and in Florida and Texas (where it went into use in 1934) for the years 1923-24 (last year before the ethylene gas process went into general use in all citrus producing States); in 1934-35 (the year in which

the Color Aded process went into general use in Florida and Texas); in 1944-45 (ten years after the use of Color Added in those two States became general), and in 1947-1948 (Annual Summary, 1955 Agricultural Marketing Service, Joint U.S.D.A. - Florida Crop and Livestock Reporting Service, Florida Department of Agriculture, p. 6):

*Orange Production (In Thousands of Boxes)*

Year	Arizona				Total
	Florida	California	Texas	Other	
1923-1924	13,150	24,234	6	295	31,819
1934-1935	15,600	45,217	650	521	61,988
1944-1945	42,800	61,650	1,150	360	109,210
1947-1948	58,400	46,610	5,200	300	110,510

The Congress has formally held that the artificial coloring of oranges with certified coal-tar food colors is an "economic necessity" to the orange industry of those States, in these words (*H. R. No. 1982, 84th Congress 2d Session, March 29, 1956, p. 2; Senate Report No. 2391, 84th Congress 2d Session, June 29, 1956, p. 1*):

*"This practice has become an economic necessity for a major segment of the orange industry, since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they were not artificially colored. Oranges so colored are plainly stamped 'color added' so that the buying public is fully appraised of the fact."* (Emphasis supplied).

This finding by the Congress was premised upon the testimony and statements before the House Com-

mitted concerned, found in the transcript thereof, as hereinafter quoted.

In the report of "*Hearing Before A Sub-Committee Of The Committee On Interstate And Foreign Commerce, House Of Representatives, 84th Congress, 2d, Session, on H.R. 7732, February 10, 1956,*" we find the following last paragraph in the statement of Mr. John T. Lesley, General Manager, Florida Citrus Exchange, Tampa, Florida, a co-operative association of citrus growers and Florida's largest shipper of oranges, handling 8 to 10 million boxes of fresh fruit in interstate commerce annually, from packing houses located in every producing area of Florida, which statement appears at page 12 of said report:

"During the 20 years we have been color-adding oranges, it has become such an accepted practice that non-colored oranges can be sold to advantage only along a limited area of the Eastern seaboard. *It is our considered opinion as Florida's largest fresh fruit marketers, that if the color-added process is banned, the State's fresh fruit marketing will be thrown into complete chaos.* Our major markets - accustomed to colored fruit - will resist the paler fruit with the inevitable result that the seaboard markets will be overloaded, causing terrific price declines to the detriment of the Florida growers. For these reasons we wholeheartedly endorse the pending legislation." (Emphasis supplied).

Testimony as to the value of and necessity for such artificial coloring of oranges is likewise set forth, in that Report, by Mr. Roscoe Skipper, Vice President and Sales Manager of Snively Groves, Inc., Winter Haven, Florida (pp. 12-13 of Report) and of Mr. Herman J. Heidrich, of the firm of Herman J. Heid-

rich and Sons, of Orlando, Florida, largest independent shipper of citrus fruits in Florida, who, referring to the possibility of shipping regreened Valencia oranges without artificial color, said (pp. 14-15): "*Marketing in this condition would be suicidal.*" (Emphasis supplied).

At page 5 of that Report, from Mr. Austin E. Anson, Executive Manager, Texas Citrus and Vegetable Growers and Shippers, Harlingen, Texas, we find the following statements:

" \* \* \* FD&C Red No. 32 has been used on all of the oranges shipped from the State of Texas for the past 18 years. This is necessary by reason of the fact that our soil and climatic conditions do not permit the oranges to mature with a natural orange color, and it is necessary to process the oranges and use an artificial coloring procedure using FD&C Red No. 32."

\* \* \*

"So far as the growers and shippers of Texas oranges are concerned *there is no substitute for this coloring process at this time, and until such time as a satisfactory substitute is developed and made available that will produce a color in line with the trade's requirements we will be unable to market our oranges, as the trade territory, supplied by Texas positively refuses to purchase any but well orange-colored oranges.*" (Emphasis supplied).

#### **Regulation Of Color Added Process**

The Color Added process went into commercial use in 1934, between biennial sessions of the Florida legislature. In May, 1935, the Florida Legislature, at the instance of the citrus industry, enacted what was known as Florida's "Color Added Act" (Florida Statutes 1935, Chapter 16.81, Secs. 1-15).



As to Maturity Standards, the Color Added Act of 1935 required a minimum solids-acid ratio of 8.5 to 1; a minimum percent of 8.5 solids in the juice, and a minimum juice content of 4.5 gals. per standard packed box.

Those standards have been raised, from time to time, always at the instance of the Florida citrus industry, until the present standards are as follows (Florida Statute 1957, Secs. 601.75 - 601.84):

# **Comparative Maturity Standards For Florida Oranges** **Throughout The Calendar Year**

<i>Nature of Test</i>	<i>Aug. 1-Oct. 31</i>	<i>Nov. 1-Nov. 15</i>	<i>Nov. 16-July 31</i>
<b>Minimum Percent Soluble Solids</b>			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	9.0	8.7	8.5
*Color Added	9.2	9.0	8.7
<b>Minimum Percent Citric Acid</b>			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	0.4	0.4	0.4
Color Added	0.5	0.5	0.5
<b>Minimum Ratio of Solids to Acid*</b>			
Federal Test (F&DA)	8.0	8.0	8.0
Non-Colored	9.5	9.65	9.75
Color Added	9.4	9.5	9.65
<b>Minimum Juice Content (Gals. per box)</b>			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	4.5	4.5	4.5
Color Added	5.0	5.0	5.0

\*When the percentage of soluble solids is higher, the ratio of soluble solids to acid may be lower, as, for example, when soluble solids are 9.2 percent, the ratio of solids to acid must be not less than 9.4 to 1, but when the soluble solids are but 9.0 percent, the ratio must be 9.65 to 1.

## **HISTORY OF COLOR ADDED PROCESS AND PROCEEDINGS WITH REGARD THERETO**

The Color Added process for enhancing the varietal color of mature oranges, by impregnating the peel thereof with a minute amount of a certified oil soluble, water insoluble, food color, was perfected in 1933, (R. 122) but due to opposition of Mr. Walter G. Campbell, then Chief of F&DA (R. 125-130) the process did not go into commercial use until the Fall of 1934, after a ruling by the Solicitor for Department of Agriculture dated February 28, 1934, settled the points of law concerned and overruled Mr. Campbell's contentions (R. 125).

We respectfully call the Court's attention to the following:

(1) The opposition of F&DA, under the direction of Mr. Walter G. Campbell, then Chief of F&DA, to *any* use of *any* coal-tar food color in *any* food, particularly the coloring of the peel of oranges. (R. 124-130)

(2) The early (1933-1937) attempted total prohibition of use of the Color Added process, sought by the Chief of F&DA, alleging the use of color to deceive the consumer, which charge was completely refuted during a series of Department of Agriculture hearings had in 1934, 1935, 1936 and 1937 (R. 124-127).

(3) The attempts of Mr. Campbell to procure from the Congress legislation that would enable F&DA to outlaw the Color Added process, by withholding certification of food colors indispensable to the operation thereof and the defeat of all such attempts (R. 127-130).

(4) The final agreement of Mr. Campbell and

Honorable J. Hardin Peterson, then Representative from the First Congressional District of Florida and now counsel in the companion case, relating to terms of the Act (R. 130) and

(5) The subsequent drafting of amendments to the pending legislation by agreement had between Mr. Campbell on the one hand, and Mr. Peterson and counsel for this Respondent on the other hand, (which amendments were finally incorporated in Section 402 (c) and Sections 406 (a) and 406 (b) of the 1938 Food, Drug and Cosmetic Act as enacted) (R. 130) each of said amendments (as then concurred in by the then Chief of F&DA) having been enacted by the Congress for the specific purpose and with the specific intent of preventing F&DA destroying the Color Added process by denying certification to colors indispensable to the operation thereof, which enactments by the Congress F&DA now seeks to contravene by removing from the list of certifiable coal-tar colors every such color that might be so used for coloring oranges.

Following enactment of the 1938 Act as thus amended, there was no further interference with Color Added by F&DA until 1953 (R. 132-133). From 1937 until now, there was no complaint to (or by) F&DA that the process was being improperly operated or improperly used or that the States of Florida and Texas were not properly policing the use of the process.

In June, 1950, the color *FD&C Violet No. 1* was added to the list of certifiable coal-tar food colors, despite adverse effects upon test animals when fed that color in large amounts, as to which F&DA said, in the Order allowing certification (Finding of Fact 13, 15 Fed. Reg. 3517, June 7, 1950):



**"The amount of color fed the animals in the test referred to in Finding No. 12 was far in excess of the amounts that any human might obtain as a result of food colored with FD&C Violet No. 1".**

**From brief filed in the Departmental proceedings by Counsel for Chase and Company and Mr. Randall Chase of Sanford, Florida, we now quote the following (R. 57):**

***"By letter dated October 13, 1952, addressed to Mr. Randall Chase, the Associate Commissioner of Food and Drugs stated in part:***

***"Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color on oranges is inherently deceptive and is contrary to the interests of both consumers and producers."***

***"We are in entire accord with that administrative position. We are in disagreement, however, with the view apparently taken at that time that the legislative history of the Act requires a conclusion that the law does not ban the use on oranges of such dyes as create an economic cheat upon the consumer."*** (Emphasis supplied.)

**Thus we find that, as late as October 13, 1952, F&DA conceded its admission of knowledge of the fact that the legislative history of the Act disclosed that, as hereinbefore set forth (p. 13 supra) it was the intent of the Congress, in enacting amendments thereto, to preclude any attack upon the use of Red 32 for coloring oranges.**

**On March 18, 1953, a conference was held in Washington pursuant to call by F&DA, to discuss the alleged toxicity of the colors FD&C Orange No. 1, FD&C Orange No. 2, FD&C Red No. 32, FD&C Yellow No. 3 and FD&C Yellow No. 4 (R. 226).**



The first mentioned Orange No. 1 is a water soluble color as to which a complaint had been received "several years" before (R. 199) being the only complaint known to F&DA as to any adverse effects upon any human being from certified coal-tar colors (R. 211-212). Orange No. 1 is of the proper hue to color oranges, but is a water-soluble color, hence will not dissolve in and color the oily and waxy constituents of the peel of an orange, but F&DA thereafter suggested (R. 149) that such water-soluble colors be "adapted" to the coloring of oranges.

The other four colors are oil-soluble colors and are the only colors ever certified that will color the peel of oranges.

(FD&C Orange No. 2 and Red No. 32 are the oil-soluble colors sought to be decertified in the instant case. Notice of final Order deleting FD&C Yellow No. 3 and FD&C Yellow No. 4 from the list of certifiable food colors, *without any hearing thereon unless objected to within 30 days, a clear-cut evasion of the procedure required by Sec. 701 (e) of the Act*, was published on May 4, 1957 (22 F. R. 3173) but was strongly objected to and action thereon was postponed by notice published in Federal Register for August 17, 1957, p. 6613.

The attention of the Court is respectfully directed to the fact that no delisting action has been taken by F&DA against any color save those that will color an orange or which F&DA mistakenly believes might be "adapted" to the coloring of oranges.)

F&DA then, in 1953, initiated a series of abbreviated tests of Red 32, which ran for 173 days only and, on the strength of erroneous conclusions premised upon results which, insofar as concerns tests at 100 and 400 ppm, we show to be incredible (p. 32-39) *infra.*)

repudiated the results of a previous series of tests made by its own pharmacologists over a period of six years (1938-1944) (Ex. 4, R. 205, 253, 254), and informed the color manufacturers that F&DA proposed to delete Red 32, Orange 2 and Orange 1 from the list of certifiable dyes (R. 226).

Notice of hearing re proposed delisting of the three colors concerned was published in the Federal Register for December 19, 1954 (R. 37).

On January 1st, 1953 *Commissioner George P. Larrick*, in an interview with a Washington newspaperman, *identified the purpose of the hearing* to be held on January 19, 1954, as being the determination of "*whether orange growers would be permitted to continue tinting their fruits orange color with coal-tar dyes.*" (R. 146-147).

When this Respondent learned, on December 18, 1953, of the real purpose of the hearings, and especially after the confirmation by Commission Larrick on January 1, 1954, it was then far too late to employ counsel and inform them as to the ramifications of a highly technical subject matter and be properly represented at the hearing on January 19, 1954, and this Respondent necessarily was not represented (R. 117-118). Also, feeding tests at proper levels, having some relation to public health, and analyses to determine the color content of all foods colored with the three colors, would have required a minimum of three year's time.

At the hearing on January 19, 1954, while admitting (R. 211-212) that they had no information as to harmfulness of the colors at "levels of ordinary normal conditions of use", F&DA presented data which proved only that test animals can be made ill by the colors when fed amounts thereof which are vastly in excess

of normal uses in foods, a result that would, of course, follow from like excessive consumption of any other substance possible of being ingested by man. (R. 205. 239-259).

Some data was presented by counsel for the color manufacturers, from the Florida Citrus Commission, as to amount of added color deposited in the peel of Color Added oranges (4 parts of color per million parts of whole oranges); in the juice, (7/100 of 1 ppm) and marmalade (1.8 ppm) when made from Color Added oranges (R. 225). No other presentations by Respondent or the citrus industry were possible, for reasons stated.

On December 22, 1954, Notice of Proposed Rule Making was signed by an Assistant Secretary. On December 30th said Notice of intent to delete the coal-tar colors FD&C Orange No. 1, Orange No. 2 and Red 32 from the list of certifiable colors, was published in the Federal Register, pp. 9352-53; R. 39.

This Respondent, on March 5, 1955, presented his Petition to Intervene, in his own name, along with Exceptions and Brief and Petition to reopen taking of testimony (R. 116-151) *all within the required time for pleading to the proposed Order*. The Exceptions, Brief and Petition presented matters and things that were self-evidently important and necessary to any proper consideration of the proposed Rule Making. (R. 116-119).

Respondent's pleadings were admitted to the record but his Petition to reopen the proceedings, so as to give Respondent and the Florida citrus industry their day in Court, was allegedly denied by a notation on the margin of the Record (p. 134, 140, 145) but no information thereof was had by Respondent until receipt of copy of printed record in the Court below.

On November 10, 1955, the Secretary issued the final order appealed from. The Order (R. 158) was published on November 16, 1955. (20 F. R. 8493) and on that same date the Department published its official Press Release HEW C-81, November 16, 1955, from which we quote:

*"FDA Commissioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods, but recent scientific investigation shows they are not harmless when fed in large amounts. (Emphasis supplied).*

*"The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, particularly hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges."*

There followed the proceedings in Fifth Circuit Court of Appeals and the decision of July 12, 1957, which held (Chief Judge Hutcheson dissenting) (1) that the word "harmless" should be construed in accordance with the rule laid down by the Supreme Court in *U. S. vs. Lexington Mill & Elevator Co.* (232 U. S. 399); (2) that the Secretary has the power to fix maximum limits of use (tolerances) for coal-tar food colors, and (3) that the Secretary has and has exercised the power to limit the use of a specific color to one specific usage, and ordered the Secretary to proceed accordingly (R. 168-187).

F&DA filed their petition for rehearing, which was denied by memorandum decision, per curiam, on August 28, 1957, Chief Judge Hutcheson again dissenting (R. 192).



The mandate issued on October 12th, 1957 and F&DA are now prosecuting their Petition to this Court.

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We respectfully submit that, in view of the foregoing, the following points are clearly established: (1) the economic necessity for the Color Added process; (2) that oranges so colored are of superior quality; (3) that the "Color Added" label is the guarantee of the States of Florida and Texas that oranges so colored are of superior quality; (4) that such oranges are, in fact, completely harmless even if the entire peel of the orange be eaten; (5) that such harmlessness is admitted by F&DA; (6) that, the attempt to prohibit the use of Red 32 for coloring oranges contributes exactly nothing to the protection of public health; that, accordingly, there was no foundation in fact for the effort of F&DA to outlaw the Color Added process by denying certification to coal-tar food colors indispensable to the operation of that process.

### **ERRORS IN PETITION FOR CERTIORARI**

By permission of the Solicitor General and of Commissioner Larrick of F&DA and Assistant General Counsel Goodrich of HEW, we recited at pp. 17-25 of our Brief In-Opposition to Certiorari, the details of research work done in good faith, by the industry, to formulate a new oil-soluble color known as Citrus Red No. 2, at a cost of some \$170,000.00, to be used for coloring oranges. We now complete that recitation by these two statements.

(1) Extraction tests run by the University of Florida Extension Service laboratories at Lake Alfred, Florida, showed that oranges colored with Citrus Red No. 2 contained, in the outer peel thereof, 01.133 parts of color per million parts of the



whole orange, as compared to 4 ppm. for F&DC Red No. 32.

(2) Application for certification of Citrus Red No. 2 was duly filed and has been rejected on the alleged grounds that it is a toxic substance, not "harmless" within the meaning of Sec. 406 (b) although pharmacologists of F&DA agree that the "no effect" feeding level is not lower than 1000 ppm. — and that is 882 times the intended use for coloring oranges.

### STATUTES INVOLVED

To complete the citation we are quoting, in full, clauses 1 and 2 of Sec. 402 (a), Secs. 402 (c), 406 (a) and 406 (b) of the Act, the Secretary's citation of "pertinent parts" in Petition For Certiorari (p.p. 3-5) having omitted portions which we deem to be not only pertinent but most important.

"Sec. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity, which is unsafe within the meaning of section 406, or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a); or \* \* \*"

"(c) If it bears or contains a coal-tar color other

than one from a batch that has been certified in accordance with regulations as provided by section 406; Provided that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit; Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination') the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." (21 U.S.C. 342)

\* \* \*

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such

extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any such added amount of such substance, be considered to be adulterated within the meaning of clause 1 of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

“(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents” (21 U.S.C. 346).

**Public Law 85-929**

**85th Congress. H. R. 13254**

**September 6, 1958**

**72 Stat. 1784.**

(Excluding Sec. 409 (g) (1) and thereafter of Sec. 4, and Secs. 5-8, inc., not deemed pertinent here).

### **AN ACT**

To protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1958".*

Sec. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451



and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

“(t) The term ‘safe’, as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal.”

Sec. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: “(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additives which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;”.

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and



the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

(c) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

Sec. 4. Chapter IV of such Act as amended by adding at the end thereof the following new section:

### **"FOOD ADDITIVES**

#### **"Unsafe Food Additives**

"Sec. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

#### **"Petition To Establish Safety**

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation pre-

scribing the conditions under which such additive may be safely used.

“(2) Such petition shall, in addition to any explanatory or supporting data, contain—

“(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

“(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive; and including specimens of its proposed labeling;

“(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

“(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

“(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

“(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

“(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food

in or on which the additive is proposed to be used.

“(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

#### “Action on the Petition

“(c) (1) The Secretary shall—

“(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reason for such action; or

“(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

“(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

"(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

"(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

"(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

"(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

"(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

"(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive

and of any substance formed in or on food because of the use of the additive;

“(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

“(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimental data.

#### “Regulation Issued on Secretary's Initiative

“(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

#### “Publication and Effective Date of Orders

“(e) Any order (including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

#### “Objections and Public Hearing

“(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable



grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

“(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

“(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier date, in which event the Secretary shall specify in the order his findings as to such conditions.

**THE TESTS UPON WHICH THE SECRETARY  
BASED HIS ORDER DO NOT JUSTIFY THE ORDER.**

The results of F&DA's tests of Red 32 are found in F&DA Exhibit 4 (R. 205, 239 - 259). We have recapitulated these tests and the alleged results thereof in the tabulation next set forth.

Test Animals <i>Diet Tests</i>	Date begun & duration	Level of Administration	Parts per Million	Reported *Effects
10 Rats (Ex. 4, R. 205, 239)	1940-102 wks.	0.10%	1,000	2, 4
20 Rats (Ex. 4, R. 205, 240)	1941- 79 wks.	0.10%	1,000	3, 4
5 Rats (Ex. 4, R. 205, 241)	1951- 10 wks.	0.25%	2,500	4
10 Rats (Ex. 4, R. 205, 241)	1951- 26 das.	0.50%	5,000	2, 4
5 Rats (Ex. 4, R. 205, 241)	1951- 12 das.	1.00%	10,000	4
5 Rats (Ex. 4, R. 205, 241)	1951- 7 das.	2.00%	20,000	4
24 Rats (Ex. 4, R. 205, 242)	1952-100 wks.	0.10%	1,000	2, 3, 4
48 Rats (Ex. 4, R. 205, 242)	1952- 20 wks.	0.25%	2,500	2, 3, 4
4 Dogs (Ex. 4, R. 205, 254)	1953- 10 mos.	0.01%	100	2***
4 Dogs (Ex. 4, R. 205, 254)	1953-148 das.	0.04%	400	1, 2, 3, 4
4 Dogs (Ex. 4, R. 205, 254)	1953- 26 das.	0.20%	2,000	1, 2, 3, 4
<i>Dosage Tests</i>				
5 Dogs (a) (Ex. 4, R. 205, 253)	1938- 5-6 yrs.	5/mg/kg/day	200**	0
1 Dog (b) (Ex. 4, R. 205, 253)	1938- 10 mos.	100 mg/kg/day	4,000**	2
	1938- 60 mos.	20 mg/kg/day	800**	0
5 Dogs (Ex. 4, R. 205, 259)	1952-single dose	100 mg		1
10 Dogs (Ex. 4, R. 205, 259)	1952-single dose	100 mg		1

\*0-No effect; 1- Diarrhea and related effects; 2-Weight loss or lack of normal gain; 3-Physical deterioration; 4-Increased mortality rate.

\*\*Conversion factor of 40 (authority F&DA, R. 210).

\*\*\*Excluding one dog which had previously been on a 2,000 p.p.m. diet for 26 days (R. 254).

(a) One dog previously fed 4,000 ppm for 36 days and 800 ppm for 27 days—then this dosage of 200 ppm as shown (R. 253).

(b) This dog received diet containing 4,000 ppm for 10 months, then put on diet containing 800 ppm of color for 60 months (R. 253).

**The Tests Run At 1,000 ppm And Higher Added Nothing To Knowledge Of Toxicity Of FD&C Red No. 32.**

We have no particular quarrel with any of the tests as made by F&DA except the two tests which were allegedly made at ratios of 100 ppm. (parts per million) and 400 ppm., hereinafter discussed.

As will be noted from the above tabulation all other tests run by F&DA were a mere repetition of tests run by the Food and Drug Administration over a period of five to six years from 1938 to 1944, together with other tests run in 1940 and 1941, except that some of the 1951 tests, notably those run at ratios of 5,000, 10,000 and 20,000 ppm. were made at levels far higher than any employed in 1938-1944.

The tests run by F&DA's own experts, in 1938-1944, had demonstrated conclusively that FD&C Red No. 32 was "harmless" when used at 800 ppm., but was not harmless when fed at 1,000. Tests run by F&DA in 1951 and 1952, at 1,000, 2,500, 5,000, 10,000 and 20,000 ppm. added nothing to knowledge of the toxicity of the colors, proving only that when fed at 1,000 ppm. the color was harmful (as had been proven in 1938-1944) and that the greater the dosage the greater the harm.

**The Tests Run By F&DA At Levels Of 100 And 400 ppm. Are Emphatically Refuted By Tests Run By Canadian Scientists in 1955 And By F&DA's Own Experts in 1938-1944.**

As to the tests at 100 ppm levels, we would first observe that the alleged result are flatly and emphatically denied by F&DA's own tests, begun in 1938 and running for five to six years into 1944, when five dogs were fed the color at 200 ppm (being double the amount fed in the 1953 short term 100 ppm test relied upon) and of the one dog fed 4,000 ppm for ten months

and, for sixty months thereafter, at 800 ppm, none of the six dogs showing any adverse effects from such feeding. (R. 205, 253 - 254).

We now discuss the two tests, run for this said purpose, at 100 ppm. and 400 ppm. levels.

The results of the 100 ppm test of 1953 are further and emphatically refuted by the Canadian tests at 300 ppm, that ran for 308 days, in 1955, without any adverse effects upon rats so fed. (See App. pp. 1-8).

As to the tests run in 1953, at 400 ppm level, we respectfully submit that this test, also, is refuted by the tests run in 1938-1944 at 800 ppm. when no adverse results attributable to such feeding were had, one dog — (a) — having been fed Red 32 at a 4000 ppm level for 36 days, then at an 800 ppm level for 27 days, then at the 200 ppm level for 5 to 6 years, while the second dog — (b) — was fed at the 4000 ppm level for 10 months, then at the 800 ppm level for 60 months.

We respectfully submit that the most that can be said for the tests at 100 ppm and 400 ppm is that, in view of the prior tests at higher levels which produced no adverse results, the evidence as to those two tests in 1953 is contradictory and most doubtful and inconclusive, falling far short of being that "substantial evidence" which is an indispensable prerequisite to the promulgation of a valid Order by the Secretary, under Sec. 701 (e) of the Act, notwithstanding which that Order reverses a construction of the word "harmless" which had obtained since 1907.

### **The Evidentiary Value Of All 1953 Tests Is Destroyed By Omission Of Data Indispensable To A Valid Finding**

We now respectfully submit that *the evidentiary value* of all of *the 1953 tests* but especially the tests on dogs (R. 256-259) run at feeding levels of 100 ppm and 400 ppm, *is completely destroyed by the lack of*



*any data whatever as to food consumption by animals on test receiving a ration containing color, as compared to feed consumption by control animals which were on a color-free ration, absent which data any conclusions premised thereon are sheer guess work — or worse.*

There is no scientific data in the record to indicate how many of the different kinds of ill effects allegedly suffered by these animals could have resulted from malnutrition attributable to refusal, by dogs on test, to eat the food containing the color, but it does not require scientific data to sustain the well-known fact that "emaciation" is an inevitable result and indicator of serious malnutrition. It will be noted from the pathological data (Ex. 4; R. 205, 254, 256) that every one of the dogs receiving various concentrations of Red 32 in their diet, during the 1953 tests, showed "emaciation" in varying degrees, from "slight" to "extreme".

The carcass of the dog that died while on a test diet containing but 100 ppm, above mentioned (No. 16376) showed "extreme emaciation". Significantly, the report also showed "dehydration", indicating refusal of water as well as food, at the end of the test period, before death. This dog had been kept on a diet containing 2,000 ppm of color until it had lost 24 percent of its body weight, in only one month, then put on a color-free diet for about 10 days, during which time it "regained some weight and improved its physical condition" after which it was put on the diet containing 100 ppm of color (Ex. 4, R. 254) which allegedly killed it.

The Court is further respectfully referred to Table I in the report of the Canadian feeding trials with ten rats, (Report p. 419, App. p. 3) where is re-



ported the effect of a diet containing Red 32 at the daily rate of 400 milligrams per kilogram of body weight (approximately 4,000 ppm in the diet, using conversion factor of 10, authority F&DA, R. 209-210). It will be noted that the comparative food consumption is meticulously stated—to tenths of a gram. By reference to data graphs at top of Report p. 420, App. 4, it will be noted that the cumulative food consumption for control and test animals is carefully plotted.

It will also be noted from Table V of Canadian experiments (Report p. 423; App. p. 7) that 12 out of 20 animals on this 4,000 ppm test survived 20 weeks (140) days at this very high feeding level, as compared to 13 surviving controls, while F&DA report on animals fed a ration only one-tenth as high in color (400 ppm) in 1953, shows 100 percent mortality in 120 to 148 days. (Ex. 4, R. 205, 255).

That F&DA fully understood the value and significance of such data is indicated by the statement that: "Each dog was weighed approximately weekly" (Ex. 4, R. 205, 254). Yet, while the tabulation of alleged results (Ex. 4, R. 205, 255) gave exact weight losses for the test animals, *there are no loss or gain weight figures for dogs on the color-free diet and there are no data whatever as to food consumption for the dogs on either the color free diet or for the dogs on feeding tests.*

We again respectfully submit that such results from feeding a ration containing 100 ppm and 400 ppm are neither credible or possible of being correct, when appraised in the light of the experiments run by Canadian Food and Drug Directorate at 300 ppm (App. 1-8) and the experiments run by F&DA during the years 1938-1944 (Ex. 4, R. 205, 253, 254) unless

there is some other factor which might explain the injury and death reported.

We respectfully submit our contention that the explanation of such results from 1953 feeding tests, as compared with the results in 1938-1944, will be found in the record of methods used: As to the 1938-1944 tests, the record shows (Ex. 4, R. 205, 253).

*"Method:* In this experiment, the dogs received the FD&C Red 32, dissolved in corn oil and administered in gelatin capsules daily except Sunday."

Feeding the color in this manner, separate from the animal's food, gave a true indication of the toxicity, or lack of toxicity, of the color, in that, there being no color therein, the offered food created no aversion thereto, or allergy therefor, caused by the odor, taste or effect of the color, and accordingly the animals ate normally when so fed. Any adverse effects would be due solely to the toxicity of the color.

As to the method used in 1953, the record reads: (Ex. 4, R. 205, 254)

*"Method:* This dye was fed at levels of 0.2 percent, 0.04 percent and 0.01 percent in a basic diet of ground laboratory chow. Each dog was housed in an individual metabolism cage, was fed and watered daily and had free access to his food. *Each dog was weighed approximately weekly.* A total of 7 females and 3 males were used." (Emphasis supplied)

When so fed, every particle of food contains its equivalent amount of the color, and, if either the odor, taste or effect of the food is unpleasant, the appetite of the animal so fed is adversely effected.

Following the above quoted material, at Exhibit 4, (R. 205, 254, 255) we find this data:

*"Results:* The four dogs which were started at

0.2 percent (2,000 ppm) FD&C Red No. 32 in their diet *ate poorly* and two were sacrificed in poor condition at 26 days after having lost respectively 28 percent and 29 percent of their initial weight. *The remaining two, which had lost respectively 24 percent and 19 percent were placed on a control diet for about 10 days. During this time they regained some weight and improved their physical condition.* Along with two additional dogs they were placed on a diet of 0.01 percent FD&C Red No. 32. One of these four dogs lost about 60 percent of its body weight and was found dead after 173 days on the 0.01 percent diet. The remaining three have lost some weight but appear in fair condition after nearly 10 months on this level. All four of the dogs on the intermediate level, 0.04 percent (400 ppm) were sacrificed in extremis at 124, 137, 148 and 148 days respectively. All had lost about 50 percent of their body weight. Sporadic but not severe diarrhea was observed during the experiment." (Emphasis and parenthetical matter supplied)

*These facts as disclosed by the record, coupled with the absence of any figures whatever as to comparative food consumption as between the control animals that received a color-free diet and the animals fed color mixed in their feed, are susceptible of but one explanation - that refusal of the dye-containing food, not the toxicity of the dye - was the basic cause for adverse results reported as to the 1953 tests - and the omission of food consumption data was no oversight, nor was it due to inadvertence.*

F&DA attempted to explain away this conflict between the results of the five to six year tests run by F&DA in 1938-1944, and their short term (173 day) tests run in 1953, and further attempted to explain

why the 1938 tests — which showed no injury to animals fed at levels as high as 800 ppm — were not appraised in 1944 as showing, as F&DA now claims those tests show, that Red 32 is not eligible for certification. To that end the following language was used in "Finding of Fact 2" of "Proposed Rule Making" as signed on December 22, 1954 and published in the Federal Register on December 30, 1954 (R. 39 at 40):

*"Because of advances in knowledge and techniques in the field of pharmacology, the Food and Drug Administration has initiated new tests to explore more fully the toxicity of the certifiable coal-tar colors. This involves the application of all techniques and procedures now considered necessary to assure proper evaluation. A number of those tests, with present-day techniques and procedures, have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32."* (Emphasis supplied).

Three Respondents in the Departmental Proceedings filed exceptions to and attacked that language in Finding of Fact 2, showing that the procedures followed in the 1938-1944 tests and in the 1953 tests were substantially identical and that the only thing "new" in the procedures was the new construction being placed on the word "harmless" by F&DA (R. 73, 82, 88-90, 142-143).

In consequence of these attacks upon the verity of the language above quoted in Finding of Fact 2, that Finding, in the final Order appealed from, was changed to read as followed (R. 158 at p. 159):

*"Since that time the Food and Drug Administration has completed additional tests to explore more fully the toxicity of the certifiable coal-tar colors.*



A number of additional tests have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32."

We further respectfully submit that in the light of this record, the results of the experiment conducted in 1953 at levels of 100 ppm and 400 ppm are entitled to neither credence nor consideration, that, as is abundantly clear, such experiments, using such methods, and such incomplete data, destroy the bona fides of F&DA's contentions; that, in these circumstances, the record made in 1953 does not constitute "substantial evidence" that the causative factor for such adverse results was the toxicity of Red 32 itself.

These tests at the most show only that F&DC Red 32 is toxic and will produce adverse effects if given in massive doses.

**FD&C Red 32 Is Admittedly "Harmless"  
As And When Used For Coloring Oranges**

The tests, however, fail wholly and completely to show any possible adverse effects from use of FD&C Red 32 in coloring oranges, where the color is used in the ratio of 4 ppm (parts per million).

This has been repeatedly admitted by F&DA as follows:

On November 16, 1955, official news release HEW-C81 of U. S. Department of Health, Education and Welfare, Food and Drug Administration, contained the following statement by F & D A Commissioner George P. Larrick (App, 21).

*"The three colors involved are harmless in the amounts ordinarily consumed in foods, but recent scientific investigation shows they are not harmless when fed in large amounts.*



"The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts, and meat products, especially hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges." (Emphasis supplied).

On February 7, 1955, when F&DA's "Proposed Rule Making", dated December 29, 1954, proposing to delist Red 32, had been seized upon as a propaganda weapon directed against the importation of Florida and Texas oranges into Europe, Commissioner George P. Larrick addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

"The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigation shows that these colors, when fed in *substantial* amounts, show evidence of toxicity. *There is, however, no evidence that, in the amount used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.*" (Emphasis supplied).

In that "Report of Hearing on HR 7732" etc., on February 10, 1956 (p. 8 supra) in his testimony before the House Committee, Commissioner George P. Larrick made the following statement (p. 18 of Report):

"Considering all of the information so far avail-

able—and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges, we cannot say that its continued use on oranges not intended for processing would pose a hazard to the public health.” (Emphasis supplied)

In that same Report in the letter of Secretary Folsom, dated February 13, 1956 (which letter was dated three days after the hearing) we find the following statement (pp. 2-3 of Report):

“While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved. \*\*\*\*” (Emphasis supplied)

#### Summation

We respectfully submit that, in the foregoing, it has been shown:

(1) That data re tests of Red 32 at feeding levels higher than 1000 ppm are irrelevant, immaterial and of no evidentiary value, for the reason that tests run in 1938-1944, and in 1940 and 1941 (p. 31 supra) proved the color Red 32 to be harmful when fed at levels of 1000 ppm., and tests at higher levels, even if correctly run and reported, could prove nothing save that injury to test animals increases as the feeding level is increased beyond 1000 ppm.

(2) That the alleged results of tests of Red 32 at feeding levels of 400 ppm. and 100 ppm. cannot possibly be correct and the omission of all-important data as to food consumption by animals on test destroys the evidentiary value thereof.

(3) That in view of (2) next above, the fact

stands clearly proven on the record that the 1938-1944 tests showed Red 32 to be harmless at 800 ppm.; that, accordingly, Finding of Fact 2 in the Secretary's final order appealed from, that

"No safe level of administration was found even in test animals for FD&C Red No. 32." (R. 158 at p. 165) was and is wholly incorrect.

(4) That, accordingly, every statement in the Secretary's Petition and brief, as to the alleged toxicity of Red 32, should be read as though the Secretary had said, instead, that "Red 32 is toxic when consumed in amounts in excess of 800 parts of color per million parts of the food colored therewith".

In view of all of the foregoing we now respectfully submit that the decision of the Fifth Circuit Court should be sustained, but the Secretary's Order should be reversed in toto.

### **NEW LEGISLATION**

**P. L. 85-929, 85th Congress, 2d. Session.  
(72 Stat. 1784)**

Since the foregoing and later sections of this Brief were written, Congress has enacted the above cited law, which was signed by the President on September 6, 1958.

We have included pertinent parts of this new law (to be cited as "Food Additives Amendment of 1958" to the 1938 FD&C Act) under "Statutes Involved" (p. 22-30 supra), and are placing this new section ahead of the main Argument in our brief, because F&DA have published, in official Press Release HEW-135, September 10, 1958, under the heading "Substances Covered", an assertion that "colors" come within the purview of this new Amendment. If this assertion be correct, and if the law comprehends "coal-tar colors", then it may be that the subject mat-

ter of this litigation has become moot, which question the Court may wish to consider first.

We are not prepared to acquiesce in such assertion by F&DA at this time, pending further study of the voluminous Congressional Hearings had on this matter of food additives, together with Senate and House Reports and the law itself, which studies cannot be completed prior to October 14th, next, when this brief must be filed.

Meantime we would call the Court's attention to certain salient facts re this new legislation which are pertinent to the issue in the instant case.

(1) Sub. Pars. (s) and (t) of Sec. 2 of the new law, amending Sec. 201 of the Act, read as follows:

“(s) The term food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food \* \* \*).

(which description undoubtedly comprehends certified coal-tar colors) and continues:

“if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as *having been adequately shown* through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; \* \* \*”  
(Emphasis supplied).

“(t) The term ‘safe’, as used in paragraph (s)

of this Section and in Section 409, has reference to the health of man or animal."

Whether or not the Congress intended that coal-tar colors be comprehended by the foregoing definition of a food additive, it must be conceded that coal-tar colors are substances added to food and become a component thereof; that the use or intended use thereof results in its "affecting the characteristics" of the food to which added by enhancing the color thereof; that coal-tar colors are used in packing and processing oranges for market.

However, in view of the flat assertions by F&DA, as hereinbefore recited (p. 39 supra) that the coal-tar colors involved in this litigation are "harmless" in the amounts ordinarily consumed in foods" (not just on oranges) and other statements by both the Secretary and F&DA (pp. 40-41 supra) that coal-tar colors as used in coloring oranges are harmless as and in the amounts so used, it seems quite clear that coal-tar colors are, *also* substances that are:

"\* \* \* generally recognized, among experts qualified by scientific training and experience to evaluate its safety (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; \* \* \* ."

Therefore, while it may finally be held that coal-tar colors are one of the "substances covered" by the new law, insofar as concerns the foregoing definition, and especially so since the Congress specifically defined exemptions therefrom but did not include coal-tar colors as an exempted substance, there remains a question as to whether the same are not exempted



from the provisions of the new law by the last above quoted language.

Moreover, the new law does not so much as refer to Sec. 402 (c), which prohibits the use in food of any coal-tar color other than one certified under the provisions of Sec. 406, (in its entirety) nor does the new law mention Section 406 (b) under which coal-tar colors are certified for use, and makes only a technical amendment to Sec. 406 (a) which requires tolerances for deleterious substances in food. Therefore, in view of F&DA's long and continued animosity toward the artificial coloring of oranges, (R. 57, 125-130) we must expect that F&DA will attempt to contend that the Congress did not intend to affect those provisions and that the word "harmless" in 406 (b) must still be construed in its most absolute sense, and that tolerance may not be established for coal-tar colors used for coloring oranges.

If such be F&DA's contention, then we respectfully invite the Court's consideration of these points:

(1) The Congress, in enacting par. (s) of Sec. 201 of the Act as thus amended, discarded the word "harmless" and substituted the words "safe under the conditions of its intended use", when writing a definition of "food additives" that, in its first clause, above quoted, undoubtedly comprehended coal-tar colors and which, likewise, comprehended every other additive that can be added to foods (except poisonous spray residues, which were already covered by Sec. 408 of the Act).

The substituted language expresses the construction placed upon the word "harmless" by F&DA from 1907 until at least October 13, 1952 (pp. 14 supra); R. 57) which construction F&DA is still applying in the case of all coal-tar colors save those used, or

which could be used, for coloring oranges. F&DA continues to certify all of those other colors, without any question, as "harmless and suitable for use in foods" although none thereof are "harmless" in the absolute sense of that word.

(2) F&DA authored the yardstick of "safe under the conditions of intended use", as applicable to all food additives, in H. R. 6747.<sup>(1)</sup>

(3) In the Secretary's brief (fn. 6, p. 12) it is stated that the Department endorsed "in principle", the provisions of H. R. 8945, 85th Congress. Sec. 5 of that bill reads:

*"(b) The Secretary shall promulgate regulations providing for the separate listing of color additives which are suitable for use in food and which are harmless under the conditions of use specified in such listing. Such regulations may provide for maximum concentrations for the use of color additive in or on any food, as necessary to protect the public health, and may provide for different maximum concentrations of the same color additive in or on different foods, dependent upon the relative importance of each color additive to the several foods in which it is used and the relative significance of those several foods in the human diet. Such regulations also shall provide for the certification of batches of listed color additives, with or without diluents, and for the exemption from certification of color additives the certification of which is not*

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(1) It is stated at p. 43, "Hearings Before A Sub-Committee Of The Committee on Interstate And Foreign Commerce, House Representatives, 85th Congress, ... With Respect To Chemical Additives in Food" held in July and August, 1957, and April 1958, that F&DA wrote H. R. 6747, which was introduced on April 9, 1957, at F&DA's request. As rewritten in the Committee, H. R. 6747 became H. R. 13,254, which became P. L. 85-929. The "yardstick" language appears in Sec. 2, par. (3) of H. R. 6747.

necessary to protect the public health." (Emphasis supplied).

(4) Insofar as concerns the fixing of tolerances, the provisions of H. R. 6747, Secs. 409 (a), (b) and (c) (1) (A) and (B), as written by F&DA (pp. 4-6 of "Hearing" cited) are substantially identical with the same numbered provisions as the same appear in P. L. 85-929. These sections empower the Secretary to fix tolerances for every conceivable substance that can be added to any and every conceivable article of food, many of which additives are more toxic than coal-tar colors, which latter are admitted by the Secretary and F&DA to be "harmless in the amounts ordinarily consumed in foods". (See pp. 39-40 supra.) Moreover, similar tolerances for coal-tar colors are provided for in the above quoted Sec. 5 (b) of H. R. 8945, which the Secretary endorses "in principle", in fn. 6, p. 12 of his brief.

The "recommendations" as to amendments to H.R. 8945 suggested by the Department on June 27, 1958, are, principally:

(a) That F&DA be empowered (by H.R. 8945) to require retesting of every certifiable coal-tar color, although the toxicity of each of said colors was exhaustively tested by highly qualified, independent research laboratories, and the data thereon submitted to F&DA with application for certification, pursuant to Sec. 135.14, F&DA Coal-Tar Color Regulations (21 C.F.R. 135, part 9) (App. 17-18) the same being thereafter reviewed and further tests made by F&DA and the same found by F&DA to be "harmless and suitable for use in foods", before the colors were admitted to certification and further notwithstanding the fact that the colors are admitted by the Secretary and F&DA to be "harm-

less in the amounts ordinarily consumed in food" (pp. 39-41 supra).

(b) That the Secretary be empowered to reject any application for the certification of any coal-tar color if the same did not have a "functional value" satisfactory to the Secretary, which would, of course, in effect, repeal Congressional approval of the use of coal-tar colors for coloring oranges as found in the first proviso amendment to Sec. 402 (c) of the Act as enacted, and the mandatory "the Secretary *shall* certify" in 406 (b), and enable the Secretary to deny certification to colors indispensable to the coloring of oranges, contrary to known intent of the Congress to insure that this not be done, as shown by the legislative history of the Act. (p. 68-76 infra).

Before the Congress (see "Hearings", fn. 1, p. 46 hereof) F&DA strongly contended for both such powers, i.e., (1) to require "functional value" as to every "food additive", as proposed by F&DA in item (ii) of Sec. 409 (b) (2) (B) and Sec. 409 (c) (3) of H.R. 6747, and (2) to compel retesting of food additives already pretested or proven by long experience to be safe for use in foods.

The Congress rejected both of said contentions by F&DA, and, instead, enacted the parenthetical matter in the last clause of par. (s) of Sec. 201 of the Act as thus amended and, in its rewrite of HR 6747 as H.R. 13254 (P.L. 85-929) deleted every reference to functional value.

This attitude of the Congress was well known to the Department when its recommendations as to H.R. 8945 were written on June 27, 1958, since a prior Committee bill, H. R. 10404, introduced in the House on January 30, 1958, likewise rejected the Department's

bid for powers to compel retesting of all foods additives and to require a "functional value", subject to the Secretary's discretion, only. There is no reason to assume that the Congress would take a different position as to coal-tar colors which are admittedly harmless under intended conditions of use.

Thus it is apparent (1) that the latest thinking of the Congress, as expressed in P.L. 85-929 was to repudiate all "absolute" standards and to require, instead, that all substances added to foods shall be "safe under the conditions of intended use" and (2) that this particular language was fathered by F&DA, who have further informed this Court that the Department endorses a similar yardstick for gauging permitted toxicity in coal-tar colors, as set forth in H. R. 8945, to wit: "harmless under the conditions of use specified in such listing".

(5) That the Secretary, by his endorsement of HR 8945, which construes the word "harmless" as meaning "harmless under the conditions of use specified in such listing" (p. 46 supra) has abandoned, everywhere save in this litigation, his contention that the word "harmless", as used in Sec. 406 (b) of the Act, requires "zero toxicity"; that the Secretary has thereby returned to that relative construction of the word "harmless" which obtained in the Department from 1907 until at least October 13, 1952 (pp. 14 supra).

That this is the deliberate thinking of the Secretary and F&DA, everywhere save in this litigation, is further evidenced by the following quotation from Senate Report No. 2422, 85th Congress, 2d. Session, August 18, 1958, re H. R. 13254, reading (p. 2):

"\*\*\*\*Conscious of the fact that any substance or, for that matter, any particular food known to be good



for the health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, *the committee agrees with the Food and Drug Administration that, instead of insisting on proof beyond any possible doubt that no harm will result under any conceivable circumstances from the use of a particular additive — which could of course, occur if an individual decided to eat a pound of salt or drink 4 gallons of pure water in an hour — the test which should determine whether or not a particular additive may be used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal, subject to the procedural safeguards provided in the bill which assure the right to hearing and judicial review.*"

Since both of the Courts below have rejected FD&A's contention that the word "harmless" must be construed in its most absolute sense, and since FD&A have now admitted that the proper yardstick is "safe under the intended condition of use", and since the Congress, by P.L. 85-929, has, in effect, fixed the construction of the word "harmless" as used in Sec. 406 (b) as meaning "safe under the conditions of intended use", we respectfully submit that the foregoing disposes of the Secretary's contention that the word "harmless", in Sec. 406 (b), should be construed in its most absolute sense as requiring "zero toxicity" as a condition precedent to certifiability of coal-tar colors.

It is further respectfully submitted that the latest thinking of the Congress on the subject of tolerances, as exemplified by enactment of P.L. 85-929, empower-

ing the Secretary to establish tolerances for every conceivable substance that might be added to any conceivable item of food, likewise rejects the contention of the Secretary, as found in his Finding of Fact 10 of Final Order appealed from (R. 164) and as contended for herein (Petition pp. 13-14; Br. pp. 26-27) that colors are used in so many foods that establishment of proper tolerances therefor is impossible.

The fact that F&DA authored those unlimited tolerance provisions in H.R. (pp. 46) supra) enacted without substantial change in P.L. 85-929, makes it quite clear that the Fifth Circuit Court of Appeals was eminently correct when it found and held R. 182 - 183):

"The Secretary, in his order, has stated that 'the Department has no means of controlling the amount of colors used in a variety of foods, drugs and cosmetics'. It is ~~not~~ apaparent that this is a problem with respect to other toxic substances which are added to food under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color."

We respectfully invite the attention of the Court to the fact that the fixing of tolerances for poisonous or deleterious substances in foods is not mandatorily required by Sec. 406 (a) of the Act unless such tolerances are necessary to the protection of the public health; that in view of the legislative and contemporaneous history of the Act (pp. 76 - 83 infra) it is clear that the word "harmless" in Sec. 406 (b) was construed by F&DA in a relative sense from 1907 until 1953, the colors being used in such minute amounts as to be, in fact, "harmless under the conditions of intended used"; that, accordingly, F&DA has never

prescribed tolerances limiting the amounts of coal-tar colors used in foods, although tolerances were fixed for poisonous substances found in the colors; that this is the only logical — and lawful — explanation of the fact that F&DA is still certifying, regularly, batches of all coal-tar colors used in all foods (save those colors used for coloring orange) without fixing any tolerance for such use.

We respectfully submit that F&DA's ruling as to coloring oranges, only, that those colors are toxic substances, requiring tolerances which cannot be fixed under existing law, constitutes a discriminatory abuse of the powers vested in the Secretary by the 1938 Act.

As stated in the beginning of this Section, F&DA asserts that the new P. L. 85-929 comprehends "colors" as being food additives.

In view of the record of F&DA's discriminatory acts re colors necessary for coloring oranges, we must expect that, whether or not coal-tar colors are comprehended by the new law, F&DA will, nevertheless, continue its efforts to prevent the use of coal-tar colors for the coloring of oranges.

We, therefore, respectfully pray that, whether or not this Honorable Court should find that coal-tar colors are comprehended within the four corners of new P.L. 85-929, the Court will now resolve each and every the issues in the instant case to the end that the citrus industry of Florida may go its way in peace, without further recurrence of unjustified attacks by F&DA upon its proper and legitimate marketing practices, which attacks have kept the Florida and Texas citrus industry, since 1953, in a state of turmoil and confusion, unable to make proper plans for the guidance of that fast growing industry. Also that industry has been put to heavy and unnecessary expense by

such improper reversal of construction of the word "harmless" by F&DA, including one item of \$170,000.00 for research to support application for certification of a new color, although the old color, FD&C Red No. 32, is admittedly "harmless" when used in the amounts ordinarily consumed in food, and for expenses of litigation, including hearings which should never have been called, since the same served only the predetermined purpose of unholding F&DA's new (1953) construction of the word "harmless", which F&DA now abandons, as to all food additives and colors save coal-tar colors necessary for coloring oranges.

## **QUESTIONS PRESENTED**

### **I.**

**DOES THE SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE HAVE AUTHORITY UNDER THE FOOD, DRUG AND COSMETICS ACT OF 1938 TO CERTIFY COAL TAR COLORS FOR LIMITED PURPOSES AND ESTABLISH TOLERANCES FOR THE USE OF SUCH COLORS FOR SUCH PURPOSE?**

### **II.**

**IS FD&C RED NO. 32 HARMLESS AND SUITABLE FOR COLORING ORANGES UNDER THE LAW AND THE FACTS IN THIS CAUSE?**

## **ARGUMENT**

### **PRELIMINARY STATEMENT**

We will present our argument on both questions presented under the following subheads:

- (a) The issues in this case.
- (b) The language of the Act.
- (c) The legislative history of the Act.

- (d) Contemporaneous administrative construction of the Act.
- (e) FD&C Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.
- (f) The Circuit Court of Appeals of the Fifth Circuit correctly decided this cause.
- (g) Conclusion. ✓
- (a) **The Issues In This Case:**

The prime issue in this case revolves around the word "harmless" as the same appears in Section 406

(b) of the 1938 Act, to-wit:

"The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in foods \* \* \*."

it being the contention of the Secretary that the word "harmless" must be construed in its *absolute* sense, that is, that before a coal-tar color is listed, it must be proven beyond question to be absolutely harmless for all uses and purposes in whatever amount used and under any and all conditions of use, it being our contention that the intent of Congress was that the word "harmless" be construed in its *relative* sense, that is, that a coal-tar color is "harmless" within contemplation of the Act if it is harmless for the purpose for which it is used and in the amounts used for such purpose.

Another issue in this case revolves around the language of Section 406 (a) and (b) and the language of Section 402 (c), it being the contention of the Secretary that he does not have the authority to list coal-tar colors for limited or particular purposes nor for the coloring of specific foods, nor to establish tolerances governing the amount of such colors to be used



for such purposes and foods, and it being our contention that the Secretary not only has such power but has in fact exercised such power and authority from the time the 1938 Act was passed until the present time.

Another issue is of course whether FD&C Red 32 is "harmless" within the contemplation of the statute for use in coloring oranges under the law and the facts in this case, it being the contention of the Secretary that since Red 32, when consumed in massive doses, is capable of producing adverse effects, it is not "harmless" and it being our contention that the evidence is conclusive; and that it is admitted, that Red 32 is completely harmless for use in coloring oranges.

#### **(b) The Language Of The Act**

Section 406 (b) of the Act of 1938 provides:

"The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents."

The first contention that we make under the language of the above sub-section is that the duty imposed upon the Secretary is a *mandatory duty*, that is, he " \* \* \* shall promulgate regulations providing for listing coal tar colors \* \* \* "

Thus we contend that if a coal tar color is "harmless and suitable for use in food" then it is the mandatory duty of the Secretary to promulgate regulations providing for its listing and certification.

We have stated that one of the issues in this case is whether or not the word "harmless" as used in the act is to be construed in its *absolute* sense or in its *relative* sense.

In another section of this brief we will discuss fully the previous administrative interpretation of the act but we think it pertinent now to cite the testimony of Doctor Herbert O. Calvery, former Chief of the Division of Pharmacology, when testifying, in 1939, re certification of coal-tar colors (R. 95):

**“Q** Are there in your opinion any coal tar colors that are harmless and suitable for use in all kinds and classes of foods, drugs and cometic?

**“A.** No, in my opinion there are no coal tar colors that are harmless and suitable for use in all kinds and classes of foods, drugs and cosmetics \* \* \*”.

and again Dr. Calvery:

**“Q.** What do you mean by the terms that you have used, harmless and suitable for use? The use to which the color is to be subjected?

**“A.** Yes, by harmless and suitable for use for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentration for which they are designed and for the purposes for which they are designed \* \* \*.”

It is too fundamental to require citations of authority that words in a statute are to be given the meaning of those words as the same are commonly used and understood in the profession or industry or science to which the statute relates.

In the testimony of Dr. Calvery, we find the meaning of the words “harmless and suitable” as they are used and understood in the scientific world when applied to coal-tar colors for coloring foods.

Thus, in substance, we find that in the field of science it is generally conceded that no coal-tar color

is harmless and suitable for all purposes, that is, harmless under all conditions and circumstances or, in other words, harmless in the absolute sense—but we also find that such colors, although not harmless in the absolute sense of the word, are “harmless and suitable” when used in proper concentrations and for purposes for which they are designed. In other words, they are “harmless” in the relative sense of the word.

In the case of *U. S. vs. Lexington Mill and Elevator Co.* 232 U. S. 399; 58 L. Ed. 658, this Court had before it a statute known as the 1906 Food and Drug Act (34 Stat at L. 768, Chap. 3915, U. S. Comp. Stat. Supp. 1911, P. 1354) which declared that an article was adulterated if it contained “\* \* \* any added poisonous or other added deleterious ingredient which may render such article injurious to health”

The defendant was alleged to have violated the statute by using a “bleaching process” employing an alleged decoloring agent which left in flour a minute amount of a poisonous and deleterious substance and it was the contention of the Secretary, then as now, that if a substance was harmful when consumed in large amounts it might not be used in foods, even when used in such minute amounts as to pose no possibility of danger to the public health. The litigation involved the validity and construction of F&DA Regulation 12 which read: “Only *harmless* colors may be used in food.” (Emphasis supplied).

After discussing the purpose of the statute, (to protect the public health) and the fact that the article (flour) which was alleged to be adulterated, was used by the old and the young, the strong and the weak, the well and the sick, and would be used in many ways, in bread, cake, gravy and broth, this Court held, in effect, that even though the added ingredient was a

poisonous and deleterious substance when used in large amounts, yet such fact did not bring the flour under the condemnation of the Statute and stated the proper interpretation to be:

"If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though have a small addition of poisonous or deleterious ingredients, may not be condemned under the act."

Thus we find that, in a case involving the addition to foods of a substance that was "harmless in the amounts ordinarily consumed in foods, but \* \* \* not harmless when fed in large amounts", and involving, also, the construction of the word "harmless" as used in F&DA Regulation 12, this Court held that the word "injurious", when used in a statute relating to food, is to be construed in its relative sense and not in an absolute sense.

Both Courts below followed that decision of this Court and both Courts below rejected the contention of the Secretary that the word "harmless" must be construed in its most absolute sense.

In the Second Circuit Court case (236 Fed. 2d 866) the Court said:

"Petitioners argue that the 1938 amendment, insofar as these sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word 'harmless' must be equated to 'added poisonous or other added deleterious ingredient which may render such article injurious to healths,' and that these words must be given the meaning assigned to them in *Wood Mfg. Co. v. United States*, 286 Fed. 84 (7th Cir. 1923). The *Wood* case adopted a standard of

relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health, as ordinarily used, and that the government was required to prove that the substance was in fact injurious as used. Respondent, on the other hand, urges that the use of a different word—'harmless'—instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. *We are unable to agree with either of these interpretations.*" (Emphasis supplied).

and cited as controlling that paragraph of this Court's decision in *U. S. vs. Lexington Mill & Elevator Co.*, (232 U. S. 399) which concludes with the above quotation therefrom.

In the Fifth Circuit Court decision (246 Fed. 2d 850, R. p. 80) the Court cited the language of the above quotation as authority for rejecting the Secretary's contention that the word harmless must be construed in its most absolute sense.

We, therefore, contend that the word "harmless" is to be construed in its relative sense and that, when applied to coal-tar colors, the word means "harmless when used in proper concentrations and for purposes for which they are designed".

Let us now see if the color Red 32, as used for the purpose for which we contend it is proper to use it, to-wit; coloring oranges, could under "any possibility, when the facts are reasonably considered, be injurious to the health of any consumer" of the oranges.

We have in previous sections of this Brief demonstrated that the tests relied upon to decertify Red 32 were unconvincing in many ways but on one point they were definitely conclusive—and that point is



decisive of this case—that is—Red 32 is harmless when used for coloring oranges.

We see no need to belabor a point as freely and fully admitted as the above fact.

The following admissions and statements establish that Red 32 is harmless when used to color orange:

On February 7, 1955, Commissioner George P. Larrick addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

*“The proposal to remove these coal-tar colors including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.”* (Emphasis supplied).

On November 16, 1955, in an official Press Release of the Department, announcing the final Order appealed from, by which Red 32 and two other colors were removed from the list of certifiable colors, Commissioner Larrick made the flat statement that those three colors are harmless not only for use in coloring oranges, but are harmless for use in coloring *all* foods, in these words (Press Release HEW C-81) (App. 22):

*“FDA Commissioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods; but recent scientific investigations shows they are not harm-*

*less when fed in large amounts.* (Emphasis supplied).

"The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, particularly hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges."

In "Report of Hearing on H. R. 7732 etc., on February 10, 1956" (p. 8 supra) in his testimony before the House Committee, Commissioner Larrick made the following statment (p. 18 of Report) :

*"Considering all of the information so far available—and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges—we cannot say that its continued use on oranges not intended for procesing would pose a hazard to the public health."* (Emphasis supplied).

In that same Report, in the letter of Secretary Folsom, dated February 13, 1956 (which letter was dated three days after the hearing) we find the following statement (pp. 2-3 of Report) :

*"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved. \* \* \**" (Emphasis supplied)..

We therefore submit that, using nothing but the language of the Act, as construed by the Courts below, we have established that Red 32 is "harmless"

for coloring oranges within the contemplation of the 1938 Act.

The Court of Appeals of the Fifth Circuit specifically held:

"The words 'harm', 'harmful', and harmless' are terms of relation." (R-179).

We submit the Court was eminently correct.

There is other significant language of the 1938 Act which further supports our contention, which is that in the entire Act citrus fruit is the only food mentioned by name. Section 402 (c), as originally enacted, read as follows:

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 406: *Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.*" (Emphasis supplied).

We submit that the above language evidences a very thorough knowledge on the part of Congress of the importance of color to the citrus industry and an intent that the color in use for coloring oranges (Red 32) be not interfered with.

We come now to the second issue in this case, that is, whether or not the Secretary has the authority under the Act of 1938 to certify a coal-tar color for a specific purpose and establish the amount of such color that may be used for such purpose.

We respectfully direct the Court's attention to the

*fact that there is not a single word in the entire Act that restricts the authority of the Secretary in this regard.*

The Court of Appeals of the Fifth Circuit specifically noted this fact and said:

*"In the order of the Secretary it is stated that there is no 'Authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges.' Although there may be no express statutory provisions authorizing the limiting of the use of a color to a single food, it is not prohibited." (Emphasis supplied) (R. 183).*

When we consider that Congress singled out one particular item of food, citrus fruit, and made specific provisions for continued use of color therefor, we cannot but be constrained to contend that the Secretary's interpretation is manifestly arbitrary and capricious. We refrain from elaborating upon the somewhat unusual spectacle of an executive officer contending for a construction of a statute that limits his authority.

Under that unrestricted authority of Section 406 of the Act, the Secretary, through F&DA, has, in Coal Tar Color Regulations (21 CFR 135; 1940) Sec. 135.02, fixed tolerances for such poisons as arsenic and lead in coal-tar food colors. Obviously, if the Secretary has authority to fix tolerances for deadly poisons such as arsenic and lead when found in coal-tar colors, then the Secretary has like authority to fix tolerances for the coal-tar colors which contain those deadly poisons, when such colors are used in food.

The Secretary was correct in fixing those tolerances for poisons in coal-tar colors. It follows, as of course, that those colors, still containing those poisons,

are not "harmless" in that absolute sense of the word contended for by the Secretary, hence the Secretary is mandatorily required to fix tolerances for those colors when used in food, unless he is prepared to return to that construction of the word "harmless", in its relative sense, which prevailed from 1907 to October 13, 1952, and which still obtains as to all colors except those used for coloring oranges, as to which latter colors, only, he asserts (1) that the colors are not harmless and (2) that he has no power to fix tolerances. All other certified coal-tar colors have been and continue to be certified, without tolerances, although no more "harmless" than Red 32.

In Sec. 406 (b) Congress mandatorily instructed certification of coal-tar colors that are "harmless and suitable for use in foods"; under Sec. 504, the colors must be "harmless and suitable for use in drugs", and under Sec. 604 the colors must be "harmless and suitable for use in cosmetics. If "harmless" as used in 406 (b) is to be construed in its absolute sense, then "harmless" as used in Secs. 504 and 604 must be similarly construed.

Yet under Sec. 135.03 of that Regulation, F&DA lists 18 colors that are certifiable as "harmless and suitable for use" in food, drugs and cosmetics; under Section 135.04 are listed scores of other coal-tar colors that are certifiable as "harmless and suitable for use" in drugs and cosmetics, while under Section 135.05 there are listed many more coal-tar colors that are certifiable as "harmless and suitable for use" in externally applied drugs and cosmetics, all three classes is being of different degrees of purity.

There are two questions that F&DA has never answered:



(1) If all certified coal-tar colors must be of zero toxicity, hence suitable for use in all three classifications, and if the Secretary has no power to restrict the use of coal-tar colors to specific uses, as he contends, by what authority are these three classes of colors thus restricted to three separate categories of use?

(2) If these colors are not of zero toxicity, why are some still being certified without fixing tolerances therefore?

In a later section of this Brief we will show by the legislative history and the former administrative interpretation of the 1938 Act that it was the intent of Congress that the Secretary should have authority to limit the use of a coal-tar color to a specific use or food and to establish tolerances as to the amount thereof for such use.

We come now to the third issue in this case, that is whether or not the Secretary has the power to establish tolerances limiting the amount of such color that may be used for such purposes as the Secretary may specify.

Again confining our argument in this section of this Brief to the language of the Act, we find that Section 402 (c) provides that a food shall be deemed to be adulterated if it contains a coal-tar color *other than one certified* in accordance with regulations *as provided in Section 406*.

We particularly direct the Court's attention to the fact that the reference is to *Section 406* in its entirety, not to any sub-sections, or part or portions of such sections, but to the entire Section 406.

The significance of this reference is that *Section 406* has two sub-sections, (a) and (b).

Sub-section (a) of Section 406 relates to the power and authority of the Secretary to limit the quantity of any poisonous or deleterious substance to be tolerated in any food where such poisonous or deleterious substance is required in the production of such food.

Sub-section (b) of Section 406 provides for certification of coal-tar colors that are harmless and suitable for use in food.

We submit that the language of the above Sections of the 1938 Act are susceptible to two constructions, both favorable to our contention that the Secretary has authority to establish tolerances for the use of Red 32 in coloring oranges.

The first construction for which we contend is that the coloring of oranges is an economic necessity and therefore the Secretary should establish tolerances for the use of color in the industry.

It is an established fact (p. 4 supra) that oranges reach their full maturity as to sweetness, size and acidity before the color of the skin changes to the yellow color that the purchasing public associates with ripeness and maturity and that the orange has passed its peak of perfection before the yellow color of the skin naturally appears and makes the same a marketable commodity, hence the necessity for artificial coloring.

The mere production of a food product is not an end of itself; the purpose of production of food is its ultimate purchase and consumption by the public. Since it is established that coloring of oranges is essential to their marketability and considering the concern of Congress for assuring the coloring and marketing of oranges it can reasonably be contended that

the phrase "required in production" embraces and contemplates that coloring is a part of the production of oranges.

The Court of Appeals of the Fifth Circuit construed the 1938 Act to require the Secretary to determine whether or not coloring of oranges was "required in production" thereof, and if so to establish tolerances for the use of suitable colors for such purpose. (R. 183).

The second construction that may be placed upon the reference in Section 402 (c) to the entire Section 406 is that Congress intended that both sub-sections of Section 406 should be applicable—that is, the Congress vested in the Secretary the power to (1) certify coal-tar colors for coloring food and (2) to establish tolerances for the use thereof in food, when, in the judgement of the Secretary, colors that are harmless under the conditions of intended use might be harmful when consumed in large quantities.

Certainly we know that *Congress showed more concern for the continued coloring of citrus fruit than for any other food product, when it specifically approved the practice of coloring citrus fruit and made special provisions for continuance of this practice and recognized that coal-tar colors are inherently toxic by forbidding their use except under strict regulation as to certification and as to amounts to be used.* We submit that, against this background of the evident purpose and intent of Congress, the Secretary's contention that Congress had no intent to give him authority to provide colors for use in coloring oranges appears somewhat arbitrary and even faintly ridiculous.

Thus when we consider nothing but the bare language of the 1938 Act it appears that:

1. F&DC No. 32 is "harmless" for coloring oranges within the contemplation of the Act.
2. The Secretary has the authority and is under the duty to certify Red 32 for coloring oranges and establish the amount that may be used for such purpose.

We will next discuss the regulatory and legislative history of the word "harmless" as used in Section 406 (b) of the 1938 Act:

### **Legislative History Of The Act.**

We now respectfully submit that the legislative history of the Act makes it very clear (1) that Congress used the word "harmless" in its relative sense and not in any "absolute" sense as contended by F&DA and (2) that the Congress mandatorily required the Secretary to establish tolerances for coal tar colors under Sec. 406 (a).

Prior to the 1938 Act, there was no specific statutory use of the word "harmless". The various regulations relating to coal-tar food colors were issued by F&DA under the general language of the 1906 Act, which provided that food would be deemed to be adulterated:

*"\*\*if it contains any added poisonous or other added deleterious ingredients which may render such article injurious to health."* (F&D Act of 1906; Sec. 7, 34 Stat. 769) (Emphasis supplied.)

However, use of the word "harmless", in the regulation of coal-tar food colors, goes back to the first coal tar color regulations ever issued on such colors under authority of the 1906 F&D Act, being Regulations 12 and 13, Bureau of Chemistry, 1907, which were reissued, in 1927, as Regulation 13, reading:

*"(a) Only harmless colors and harmless preser-*

vatives may be used in articles of food." (originally

“(b) A color, preservative, or other substance, Reg. 12).

even though *harmless*, shall not be used in the preparation of any food in a manner whereby damage or inferiority is concealed.” (originally Reg. 13). (Emphasis ours).

The same or equivalent language was carried forward in reissues of such regulations and remained in effect (See Dunn, p. 1348) until the 1938 Act was enacted, when the word “harmless” was merely transplanted into the Act, in Subsection 406 (b), reading:

“(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are *harmless* and suitable for use in food and for the certification of batches of such colors, with or without *harmless diluents*.” (Emphasis ours).

The purpose and intent of the Congress in enacting section 406 (b) was stated in clear cut, direct terms. From the first hearing on the bill S-1944 (73rd Congress, 1st Session, 1933, see Dunn, Ap. B. p. 1066) until the final mention of the section in the House Report on Bill S-5 as enacted (75th Congress, 3rd Session, 1938, see Dunn, p. 820) that purpose and intent was emphasized repeatedly, in such words as these:

*“This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law” \* \* \*. (Dunn, p. 820, emphasis ours).*

The testimony of Mr. W. G. Campbell, Chief of F&DA, before the Senate Committee on Commerce, on December 7, 1933, on this subject, reads (Dunn, pp. 1065-66).



"MR. CAMPBELL: \* \* \* "Paragraph (d) of this act makes it an offense to use a coal-tar other than one from a batch that has been certified by the Secretary in accordance with the regulations as hereinafter provided.

"In section 10, to which we referred, on page 14, you will find, in the record paragraph of that section, line 8, page 15, that the Secretary is authorized to make regulations after notice and hearing, for the *certification of coal-tar colors which he finds to be harmless* for use in food."

"The CHAIRMAN. That is not in the law now?

"Mr. CAMPBELL. That is not in the law now.

The CHAIRMAN. It is there by regulation?

"Mr. CAMPBELL. By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, in *recognition of the impurities to be extensively found in a great many coal tar colors and the poisonous character of some of the colors themselves*, issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be non toxic and free from deleterious ingredients. These regulations established the practice of examining the *purity and safety* of coal-tar (colors) as a method for the protection of the public.

"*It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907.*" (Dunn, pp. 1065-66) (Emphasis supplied.)

We now respectfully direct the attention of the Court to the fact that when Mr. Campbell thus testified the decision of this Court in the *Lexington Mill case*, 232 U. S. 399, had been the law on this point for 19 years; that the principles there laid down by the

*Court were an integral part of the "practice" which Mr. Campbell was here asking the Congress to reaffirm by legislative action and continue in effect.*

When read in the light of these statements, there is not a word in the legislative history of the Act which supports the contention of F&DA herein that the Congress intended to limit certification of coal-tar food colors to those that were "harmless" in the absolute sense of that word. Until at least October 13, 1952 (R. 57) F&DA were stately of the same conviction.

Since Orange 1, decertified by the order appealed from, and Yellow OB (FD&C Yellow No. 4) and Yellow AB (FD&C Yellow No. 3) (now sought to be decertified per "Proposed Rule Making" published in Federal Register for May 4th, 1957, p. 3173); are three of the colors certified in those early days, it is apparent that the word "harmless" was always used in its "relative" sense, since certification would have been prohibited if the word "harmless" had been used in its "absolute" sense.

Since five years have elapsed since F&DA made its initial attempt in 1953 to construe the word "harmless" in an "absolute" sense, rather than the "relative" sense theretofore followed, and since 12 coal-tar colors, all containing such poison, are still on the certified list and unchallenged as to their "harmlessness", it follows that F&DA is still construing the word "harmless" in its "relative" sense insofar as those 12 coal-tar colors are concerned.

We now further respectfully submit that, specifically, the last amendments to Sec. 402 (c), 406 (a) and 406 (b), prior to enactment of the Act, make it very clear that each of those amendments were enacted pursuant to a very evident purpose and intent of the Con-

gress to insure the continued used of coal-tar colors for coloring citrus fruit.

The pertinent parts of the bill "Senate 5 — 75th Congress" as it passed the Senate on March 9, 1937, (Dunn, p. 746) read as follows:

Sec. 11 (enacted as section 402) then read:

"Sec. 11. A food shall be deemed to be adulterated:

"(c) If it contains a coal tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 15." (Dunn 782).

Sec. 15 (enacted as Sec. 406) then read:

"Sec. 15 (a) Any contaminating, poisonous, or deleterious substance added to any food, except when such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purpose of the application of section 11 (a), but when such substance is so required or cannot be so avoided, the Secretary *is authorized* to promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health. \* \* \*

"(b) The Secretary *is hereby authorized* to promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in foods." (Dunn, p. 785). (Emphasis supplied).

The Bill went to the House Committee on Interstate and Foreign Commerce on March 10, 1937, where it remained until August 20th, 1937, when that Committee presented to the House a revised bill (Dunn, p. 751) arrived at by striking everything in the Bill

as passed by the Senate except the title and enacting clause and inserting a House Committee draft.

We find these amendments in this new House draft of the bill, recommended to the consideration of the House on August 20th, 1937 (Dunn, 752) in the sections here concerned:

"Sec. 402. A food shall be deemed to be adulterated—

"(c) If it *bears or contains* a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided, that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit.*" (Emphasized matter is amendment concerned).

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of *clause (2) of section 402 (a)*; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for the purpose of the application of *clause 2 of Sec. 402 (a)*. While such a regulation is in effect, limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing

*any added amount of such substance; be considered to be adulterated within the meaning of clause (1) of Sec. 402 (a) \* \* \**. (Emphasized matter indicates amendment concerned).

“(b) The Secretary *shall* promulgate regulations providing for the listing of coal-tar colors that are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.” (Emphasized matter indicates amendment concerned).

The purpose and intent of the Congress in adding the “proviso” clause to Sec. 402 (c) is crystal clear. The language used is susceptible of but one interpretation — that coal-tar colors were then being used to color citrus fruit, which practice enjoyed Congressional approval; that application for certification of a color so used had been made but had not been acted upon by the Secretary; that to the end that such coloring practice be not stopped or interfered with by the failure or refusal of a Secretary to certify new colors, Congress was granting special authority for the continued use of that color until the application for certification thereof had been acted upon by the Secretary.

When the corollary amendments to Section 406 are considered in the light of the addition of that “proviso” amendment to Section 402 (c), the purpose and intent of the Congress in enacting those amendments is likewise crystal clear.

As admitted by the Secretary's petition (PB. 19, lines 7-9 of designated par. “A”, and cited authorities) Congress was fully informed and advised that: “Coal tar colors have always been recognized as having potentialities of danger” Those coal-tar colors were known to contain small amounts of arsenic and lead, together with other deleterious substances pro-



duced by side reactions during manufacture (see F&DA Coal-Tar Color Regulations (Sec. 135.02, 135.03; app. 9 - 14). Sec. 201 (f) defines "food" as "(1) articles used for food or drink for man or other animals, \* \* \* (3) articles used for components of any such article", under which definition coal-tar colors are, of course, a food.

Coal-tar colors containing such poisonous or deleterious substances were, therefore, clearly within the interdiction of section 402 (a) unless tolerances were prescribed therefor. So long as the statutory power to fix tolerances and certify colors was permissive or discretionary with the Secretary, the use of coal-tar colors for the coloring of citrus fruits could be stopped or interfered with by the failure or refusal of a Secretary to establish necessary tolerances therefor, or to certify needed colors.

The Congress, therefore, pursuant to its purpose and intent, so clearly evidenced by the amendment to section 402 (c), to insure the continued use of coal-tar colors for coloring citrus fruit, amended Section 406 (a) by changing the permissive "the Secretary is authorized" to the mandatory "the Secretary *shall*" and by spelling out the exemption accorded to foods containing such tolerated amounts of deleterious substances.

Pursuant to the same intent, Congress also amended Section 406 (b) by again changing the permissive "the Secretary is hereby authorized" to the mandatory "the Secretary *shall*".

That the amendments to Sections 402 (c) and 406 (b) are of the same origin and purpose, is further evidenced by the fact that the proviso amendment to section 402 (c) and section 406 (b) both refer to the

"listing" of certifiable colors, "listing" being a word never before used in the proposed legislation.

Although these amendments were of decided importance, especially to F&DA, Dunn reports no reference whatever to those amendments in any Report or debate on the Act. The majority Report to the House (Dunn, p. 819-820) and the Minority Report (Dunn, 834) are silent thereon, and there is no mention thereof in the prolonged debate in the House (Dunn, 840-963), nor, the Senate having refused to agree to another House amendment, in the Conference Report and statement in the House (Dunn, 970-996). There was no debate in the Senate on either the House rewrite or the conference report. (See, here, R. 130).

Since all of the coal-tar colors certified prior to enactment of the 1938 Act (including Orange No. 1 and Orange No. 2) were recertified in 1939, it is very clear that the Department did not ask, nor did Congress enact, any new requirement of zero toxicity; that, as Mr. Campbell and the Senate Report stated, Congress was asked to give — and Congress gave — legislative sanction to the prior Department practices re certification of colors — that and no more.

In the light of the foregoing, we will now discuss:

**(c) The Legislative History of the Act, and**

**(d) Contemporaneous Administrative Construction of the Act.**

We will consider these two matters together for the sake of brevity and because the legislative history of the 1938 Act clearly evidences the intent of Congress as to the issues of this case and because that intent was so well known to the officials charged with the responsibility of administering the Act that there was no variance between the intent of the Congress and the administration of the Act by such officials.

It is our basic contention that, on each and every issue in this case, F&DA has completely changed its position, reversed its former contentions, and departed from its previous interpretations of the law and that such changes, reversals and departures have resulted in defeating the clear intent of the Congress.

Let us first direct our attention to the word "harmless" as the same appears in Section 406 (b).

Almost contemporaneously with the passage of the 1938 Act Dr. Herbert O. Calvery, F&DA's Chief of the Division of Pharmacology, testified re basis for certification of coal-tar colors, as follows (U. S. D. A. FD&C No. 4, February 7, 1939). (R. 95-6):

"Q. What do you mean by the terms, that you have used, 'harmless and suitable for use'? The use to which the color is to be subjected?

"A. Yes, by 'harmless and suitable for use' for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed and for the purposes for which they are designed.

"Q. In considering the amount used, does the tinctorial properties of these coal-tar colors have some bearing on the amount used?

"A. Yes, the tinctorial properties of the coal-tar colors is such that when they are used in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics.

"Q. Dr. Calvery, how do you arrive at percentage

of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?

"A. We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drug manufacturers, and after learning from them what the percentages are, which in most cases are a fraction of a per cent, we based our reasoning on that premise. *The colors are not certified for use as colors to be consumed as colors. They are certified—at least we are permitting the listing of these for certification—on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages.*

"Q. Now, have you reached an opinion as to the maximum percentages of coal tar colors which would be allowable respectively in foods, drugs and cosmetics, in view of the tolerances for impurities which have been established in these present regulations.

"A. No, we haven't reached a definite conclusion as to what is the maximum that may be permitted. *It is our understanding as I pointed out before that these colors are used in relatively small amounts, in most cases only a fraction of one per cent in the finished product.*

"— If manufacturing processes and the use of these colors should change to such an extent that more than these amounts should be used, on or which we have actually taken into consideration in considering the toxicity of these colors, *if that should change to an extent whereby larger amounts would be used, I think there would be no question but that we would have to take that into considera-*

tion in order of time and *consider amendments to the present regulation.*" (Emphasis supplied).

Thus it appears that the contemporaneous interpretation of the law was that "harmless" was used in the 1938 Act in its relative sense; that coal-tar colors could be certified for specific purposes and that when necessary the Secretary had authority to regulate the amount to be used, and that the statute not only authorized but directed and required the fixing of tolerances for color-tar colors, when necessary for the protection of the public health.

Let us resort to a comparison of *present* interpretation of the Secretary and of the past interpretations:

Finding of Fact 10 of the Order of the Secretary is as follows (R. 158):

"10. There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurrence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges." (R. 164).

The comparison of the *present* interpretation of the Secretary with the testimony of Dr. Calvery above quoted is rather startling, but let us look, for further contrast, to the testimony of Hon. Walter G. Campbell,



Chief of Food and Drug Administration and principal legislative spokesman for the Department, from 1933 through to adoption of the Act in 1938 and, thereafter, the officer charged with initial administration of the Act. Mr. Campbell testified before the Senate Committee on Labor and Commerce on December 30, 1933, re Senate Bill 1944, as to the necessity that FD&A be empowered to establish tolerances—the section under discussion being almost identical with present Section 406 (Dunn, pp. 1056-57):

*“This is an extremely important, in fact, one of the most important provisions of this bill. It may be impossible to preclude absolutely poisonous ingredients from food. Some of the deleterious ingredients with which we have to deal are to be found universally. But it is important that they not only be kept to such a low limit in each article of food in which they may be found that that article of food itself may not be dangerous to health, but important, furthermore, that the total intake of poisons by the consumer of foods from all sources be restricted to an amount which will not be dangerous to health. \* \* \**”

*“You know the extent to which this matter has been agitated; fruit and vegetable growers have followed the instructions issued them by official agencies for the use of insecticides. It became the obligation of the same agencies then to advise the growers about methods by which this spray residue could be removed. Methods more or less satisfactory have been devised, and in the majority of cases, particularly the fruit products, the amount of residue encountered now is below the tolerance which has been determined as safe for consumption. But, Mr. Chairman, and this is another important argu-*

ment for this particular paragraph, *under the terms of the present law we are able to consider only a single commodity. If that single article of food does not contain poison in excess of the tolerance that has been determined as safe for consumption, it is not in violation of the present law. But suppose that article contains just a little less than the safe tolerance. Multiply that by the number of articles of food also containing traces of added poisons which constitute our daily diet, and you can get some conception of what the general intake of poisonous substances would be.*" (Emphasis supplied).

Thus when F&DA was seeking, in 1933, to enlarge its powers, it solicited from the Congress and was granted power to prescribe tolerances for *every* possibly deleterious substance that could by any chance find its way into *any* article of food in the Nation's dietary, and premised its solicitation upon the urgent necessity for establishing tolerances that would comprehend "the total intake of poisons by the consumer of foods from all sources".

But when F&DA wishes to evade the mandatory directive of the Congress to establish such tolerances for coal-tar colors used for coloring oranges, which colors are admittedly harmless as used, the task becomes impossible, beyond the powers of F&DA, because the color is used in so many different foods.

The Fifth Circuit Court cut through such evasions with the following comment. (R. 168 at p. 182):

"The Secretary, in his order, has stated that 'the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics.' It is not apparent that this is a problem with respect to other toxic substances which are added to foods under tolerances fixed

by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color.' \* \* \* ."

But we do not need to rely only upon the testimony of Mr. Campbell and Dr. Calvery to show the contemporaneous interpretation of the Act. The official publications of F&DA bear witness to the changes, reversals and departures of the Secretary from previous interpretations.

In the official publication "**Coal-Tar Color Regulations**" (21 CFR 135) promulgated and published August 27, 1940, and still in effect, we find that tolerances were established and coal-tar colors restricted to specific purposes as follows:

(1) Sec. 135.02 prescribes tolerances for arsenic, lead and other heavy metals, in *all-certified coal-tar colors*. (App. 9-10).

(2) Sec. 135.03, under "Specifications" for each coal-tar color certified for use in foods, drugs and cosmetics, establishes tolerances for other deleterious substances found therein. (App. 11-13).

(3) Sec. 136.03 also states general authority for certification of all FD&C colors (app. 10-11) but makes certification subject to the restrictions of subpar. (c) thereof, which reads:

(c) No lake listed in sub-section (a) shall be certified for any use in food except *external application to shell eggs*. (Emphasis supplied).

Thus we see that F&DA in 1940 definitely restricted the use of certain colors to external application to shell eggs, but now contend that there is no authority to restrict the use of a coal-tar color to the one purpose of external application to the skins of oranges, as heretofore mentioned (R. 158 at 164).



In the same official publication we find in Section 135.11 (4) (page 41) the provisions for labeling coal-tar colors and specific provisions being made that the label show *the specific food for which certification of the color is sought*. (App. 17).

Again, in Sec. 135.06 (3) under Mixtures Which May Be Certified, it is clearly contemplated that mixtures shall be certified for use only in specified food.

Thus we see that the Secretary has prescribed tolerances for the poisonous ingredients of coal-tar colors and has limited colors containing certain ingredients to a particular purpose and actually made provision in his regulations for labeling coal-tar colors for use in a specified food.

We submit therefore that the evidence is conclusive that, contemporaneously with the passage of the Act, the interpretation of the Act by the Administrative agency was that tolerances could be fixed for use of coal-tar colors and that a coal-tar color could be restricted to a particular purpose and for a specific food.

**(e) F&DC Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.**

We have heretofore analyzed the tests upon which the Secretary based his order and will not burden the Court with repeating that portion that demonstrates that the tests are inconclusive and indecisive.

One further reason why we need not further argue the tests is of course that we need not argue that which is admitted — and the correctness of our contentions on the only factual issue in this case is fully admitted — that is, that there is no proof whatever that F&DC Red No. 32 is harmful in any way when used for the purpose of coloring oranges.

These admissions have been quoted before but we repeat them for convenience:

The following admissions and statements establish that Red 32 is harmless when used to color oranges.

On February 7, 1955, Commissioner George P. Larrick of F&DA addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

*"The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."* (Emphasis supplied).

In the "Report of Hearing on H. R. 7732" etc., on February 10, 1956 (p. 8 supra) in his testimony before the House Committee, Commissioner George P. Larrick made the following statement (p. 18 of Report):

*"Considering all of the information so far available - and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges - we cannot say that its continued use on oranges not intended for processing would pose a hazard to the public health."* (Emphasis supplied).

In that same Report in the letter of Secretary Folsom, dated February 13, 1956, (which letter was dat-



ed three days after the hearing) we find the following statement (pp. 2-3 of Report):

*"While the scientific evidence so far available does not establish that the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved. \*\*\*"*  
(Emphasis supplied).

We submit therefore that it conclusively appears that F&DC Red No. 32 is harmless and suitable for use in coloring oranges.

**(f) The Court of Appeals of the Fifth Circuit correctly decided the issues in this case.**

There are but two major issues in this case, one of law and one of fact.

The issue of law is one of construction and interpretation and revolves around the intent of Congress as expressed in the word "harmless."

The issue of fact is whether or not F&DC Red No. 32 is "harmless" within the meaning of that word as used in the 1938 Act when such color is used for coloring oranges.

We have cited the opinion of this Court in the Lexington Mill case (pp. 57-58 supra) which we submit is conclusive on the issue of law and the Court of Appeals of the Fifth Circuit followed that case in holding that the word "harmless" was to be construed in a relative sense.

In deciding this point the Fifth Circuit Court said:

*"The words 'harm', 'harmful', and 'harmless' are terms of relation. In this sense they resemble 'wrong' and 'wrongful'. Red 32 is harmless, i.e. not harmful, to all persons under the protection of the*

Act while it remains in the vat or the vial. An injury must occur before harm results. The color Red 32 becomes harmful, i.e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such small quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he had he consumed none of it.

“*In United States v. Lexington Mill & Elevator Co., supra*, the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient, but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it ‘contain any added poisonous or other added deleterious ingredient which may render such article injurious to health’. It was contended there, as it is contended here, that it is the character—not the quantity—of the added substance which is to determine the case. This contention was rejected. The Court said:

“‘If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the Act.’ (232 U. S. 399, at 411).

“As in the *Lexington Mill case*, it was held in the Seventh Circuit that ‘injurious’ is a relative rather than an absolute term. *W. B. Wood Mfg. Co. v. United States*, 7 Cir. 1923, 286 F. 84. We think ‘harmless’ is also to be so construed.” (R. 179-180).



On the issue of fact, that is, whether F&DC Red No. 32 is harmless for use in coloring oranges, the Fifth Circuit Court held:

"The Secretary would concede, apparently, the possibility that a person might consume Red 32 in such small quantities that no hazard to health would result. His guarded statement is that 'the evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved.' *The Commissioner of Food and Drugs has admitted that there was no evidence of injury to consumers of colored oranges.* The Secretary has made no effort to ascertain whether or not there is, in fact, any likelihood of injury to the health of persons who consume oranges colored with Red 32. Taking the position that no quantitative test is authorized, the Secretary disclaims any power to fix a tolerance for the use of Red 32 in the coloring of oranges or for any other particular use. Under this theory it would make no difference whether or not there was a minimum quantity of Red 32 which would not be injurious. *Malum in uno, malum in omnibus*, is the departmental canon of construction.

"*Unless the quantities of Red 32 used in the coloring of oranges are dangerous to public health, the objects and purposes of the Act will not be promoted by a construction which prohibits that use in such quantities.* The statute which we construe provides for the fixing of tolerances for added poisonous and deleterious substances in the production of food and, by a 1954 amendment, for the fixing of tolerances for poisonous pesticides on raw agricultural commodities. *We cannot see how the ob-*

*jects and purposes of the statute would be furthered by a construction which permits safe, i. e., harmless, quantities of poisons other than coal-tar colors to be added to food where required in its production, and which permits safe tolerances of poisons for pesticides, but prohibits the use of a coal-tar color in the most minute and harmless quantity because it is harmful and injurious in large quantities. Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and an injustice. There is, we think, a more reasonable interpretation of the Act."* (Emphasis supplied).

We submit that the Court of Appeals of the Fifth Circuit was correct.

### **Reply To Petitioner's Brief**

Since our foregoing brief was written, we have received copy of Petitioner's brief and now append our reply to a few of the statements therein which are not in accord with the record.

*Re par. at p. 9, beginning: "The Secretary refused to reopen":*

We respectfully suggest that another reason why the Secretary refused to reopen the Hearings and allow the citrus industry its day in Court may very well have been that a principal witness for Respondent would, necessarily, have been Mr. Walter G. Campbell, Chief of F&DA from 1933 until 1944, whose testimony re allegations recited in Petition to reopen and in Exceptions (R. 116-119; 125-130) could have



wrecked F&DA's contention that Congress used the word "harmless" in its most absolute sense, since Mr. Campbell was Departmental spokesman for the legislation from 1933 until enactment in 1938. (See statement of Secretary Wallace, before Committee, December 7, 1933, Dunn, 1049-1050).

*Re Footnotes 12, Petitioner's Brief p. 34:*

The "mottling" of Easter Egg colors was not mentioned in the Order published in the Federal Register. The reference to 1934 seizure of uncertified house paints used for coloring Easter eggs, is irrelevant, that situation having been cured by Sec. 402 (c) of the 1938 Act.

The pertinent fact is that *whatever the reason for restricting the use of "lakes" to the coloring of Easter eggs, such use was so restricted and the Regulations contemplated that other colors might be similarly restricted to one usage on one food — but the Secretary has flatly refused to accord to colors used for coloring oranges an equality of treatment with colors certified for use in coloring Easter eggs.*

*Re Footnote 20,, p. 47 of Petitioner's Brief:*

F & D A's contention that the word "harmless" should be construed in its absolute sense, was rejected by the June, 1956, report (p. 17) of the *ad hoc* Advisory Committee of the National Academy of Sciences-National Research Committee, appointed, on F&DA's request, to review F&DA's Research Program on Coal-Tar Dyes, to which Report the Secretary refers in this foot note. That Committee said:

... "This committee feels compelled to indicate that *certification of a compound as 'harmless and suitable for use' in foods, drugs and cosmetics as required under the present law is unrealistic unless*



*the level of use is specified. Under a rigid interpretation of this directive many components of ordinary diet could not be certified. Attempts by FDA to conform to such idealistic standards of absolute safety serves to direct research along unproductive lines. In practice it is possible to certify many useful compounds only on the assumption that they will be used in customary concentrations. However, a manufacturer might assume that he may safely incorporate in his product any quantity of a certified dye. FDA will continue to be handicapped in setting up a sound research program designed to determine the safety of colors for human use and consumption so long as it is denied authority under the law to specify levels of use . . ."* (Emphasis supplied).

The Committee, of course, merely assumed that the 1938 Act does not authorize the fixing of tolerances for coal-tar colors used in food, which we have shown to be incorrect. (pp. 62-65 supra).

*Re statement at p. 2 of Petitioner's brief:*

*"The Secretary could not borrow the criteria (for tolerances) from Sec. 406 (a), because toxic colors are neither required in production nor unavoidable in good manufacturing practice."* (Parenthetical matter supplied).

This is an amazing statement. There are thousands of foods, beverages and confectionaries that are colored, daily, by various certified coal-tar colors. None of these colors are "harmless" in the absolute sense of the word, all requiring tolerances for arsenic, lead and heavy metals, fixed under Sec. 135.02, and for other deleterious substances under Sec. 135.03, of Coal-Tar Color Regulations (21 C.F.R. 135, part 9). Coal-tar colors are used for one purpose only — to improve "eye-appeal" and, thereby, the marketability of the

product so colored. If the Secretary's statement re use of coal-tar colors for coloring oranges, without tolerances, as above quoted, is correct, then it is likewise true that the use of coal-tar colors in such foods, beverages and confections is "neither required in production nor unavoidable in good manufacturing practice."

Yet F&DA continues to certify daily, all coal-tar colors used in the production or manufacture of such articles, where the color is consumed in toto, while refusing to certify Red 32, equally "harmless", for use in coloring oranges, where the color-containing peel is seldom eaten.

We respectfully submit that such discrimination by F&DA against the coloring of oranges — one item from a list of thousands of foods similarly colored, for the same purpose, — constitutes a deplorable abuse by the Secretary of the powers vested in him by the Act, equalled only by his refusal to accord to colors necessary for coloring oranges, found by the Congress to be an "economic necessity" to a great industry, an equality of treatment with colors used for coloring Easter eggs. (p. 34 supra).

*Re Footnote 21, p. 48 of Petitioner's Brief:*

This is, of course, an insinuation that artificially colored oranges carry far more color in the peel than the 4 ppm reported.

This record discloses (R. 141) that F&DA is itself responsible for the use of the figure of 4 ppm. as being the amount of color found in the peel of an orange.

*Re Petitioner's Sec. III, pp. 44-49.*

The Secretary's brief, per above and elsewhere, stresses the burden allegedly improperly placed upon the Secretary by the Court below, of bearing the bur-



den of proof that coal-tar colors are, in fact, harmful to human health, before delisting said colors.

This argument ignores the fact that the industry has already once borne the burden of proof that the colors are harmless, by complying with the rigid requirements of Sec. 135-14 of F&DA's Coal-Tar Color Regulations (App. 17-18) (at a cost in a recent case of some \$170,000.00; p. 19 supra) following which the data thus submitted was rechecked by F&DA and a regulation promulgated listing the colors as certifiable.

*The Secretary is now the proponent of another regulation seeking to delist certain colors on the list. Sec. 7 (c) of Administrative Procedures Act (5 U.S.C.A. 1006) reads in part:*

*"(c) . . . Except as statutes otherwise provide the proponent of a rule or order shall have the burden of proof . . . "*

## CONCLUSION

1. This cause presents two primary issues, one of law, to-wit: the meaning of the word "harmless", and one of fact, to-wit, whether or not FD&C Red No. 32 is harmless and suitable for use in coloring oranges.

2. The language of the 1938 Act, the legislative history of said Act and the previous administrative interpretations all conclusively demonstrate that Congress intended the word "harmless" to be construed in its relative sense.

3. The Secretary admits that F&DC Red No. 32 is harmless in the amounts used for the coloring of oranges.

4. The 1938 Act does not prohibit the Secretary from certifying coal tar colors for limited purposes or

from prescribing the amounts of such color for such purposes.

5. The Congress took special note of the need of the citrus industry for coal tar colors and made special provisions therefor.

6. It is evident from the record in this case that absent an express prohibition in the 1938 Act against the Secretary certifying coal tar colors for limited or specific purposes, there is every reason why the Secretary should make such certification.

7. The judgment of the Court of Appeals of the Fifth Circuit should be affirmed.

Respectfully submitted,

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Of Counsel for Respondent  
**Frank R. Schell**

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Tallahassee, Florida  
Of Counsel

**CERTIFICATE OF SERVICE**

I hereby certify that on this 10th day of October, A. D., 1958, I have served two copies of the foregoing brief on each of the following persons, mail, postage prepaid:

Honorable Arthur S. Flemming,  
Department of Health, Education and Welfare,  
Washington, D. C.

Honorable J. Lee Rankin,  
The Solicitor General,  
Washington, D. C.

Honorable Malcolm Anderson,  
Assistant Attorney General,  
Washington, D. C.

Honorable Beatrice Rosenberg, Attorney,  
Department of Justice,  
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Honorable William W. Goodrich,  
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Tampa, Florida  
October 10, 1958



## APPENDIX

Reprinted from *The Journal of Pharmacy and Pharmacology*, 1956, 8, pp. 417-424

### CHRONIC TOXICITY STUDIES ON FOOD COLOURS

PART II. OBSERVATIONS ON THE TOXICITY OF FD&C GREEN No. 2 (LIGHT GREEN SF YELLOWISH), FD&C ORANGE No. 2 (ORANGE SS) AND FD&C RED No. 32 (OIL RED XO) IN RATS

BY M. G. ALLMARK, H. C. GRICE AND W. A. MANNELL

*From the Food and Drug Laboratories, Department of National Health and Welfare, Canada*

Received January 10, 1956

THIS paper describes further studies on the chronic toxicity of food colours. In Part I of this series some chronic effects of Oil Yellow AB and OB in rats were reported<sup>1</sup>. It has previously been reported by other workers that some colours belonging to the azo and triphenylmethane classes caused tumours to develop in animals after subcutaneous injections<sup>2,3</sup>. As some of these colours are being used in food it was thought worthwhile to examine them for chronic oral effects in rats. The effects of the oral administration of FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 on growth, food consumption, food efficiency, blood haemoglobin, and on the pathology of a number of organs are presented in this paper.

#### METHODS

The methods employed were similar to those reported for the two yellow colours<sup>1</sup>. The food colours were incorporated in the laboratory diet in the following concentrations: FD&C Green No. 2, 0.03, 1.5 and 3.0 per cent; FD&C Orange No. 2 and FD&C Red No. 32, 0.03, 0.75 and 1.5 per cent. The rats were approximately five to six weeks of age at the start of the experiment. The animals were kept in groups of two to a cage and were given free access to their respective diets and water. Their body weight and food consumption were recorded weekly. For more accurate evaluation of food consumption it would have been preferable to place only one rat in a cage, but this was not possible. Post-mortem examinations were made where possible on rats which died on test. All surviving rats were killed at the end of the experiments and post-mortem examinations were made. Many of the organs were weighed and prepared for histological examination. As a result of an unfortunate accident at the end of the fourth week to the male rats on a dietary concentration of 1.5 per cent. FD&C Green No. 2, data on these rats are not included.

#### RESULTS AND DISCUSSION

##### *The Effect on Growth Rate, Food Consumption and Food Efficiency*

Growth, food consumption and food efficiency curves for the groups receiving the various dietary concentrations of the three colours are shown in Figures 1 and 2. Growth rate, food consumption and food

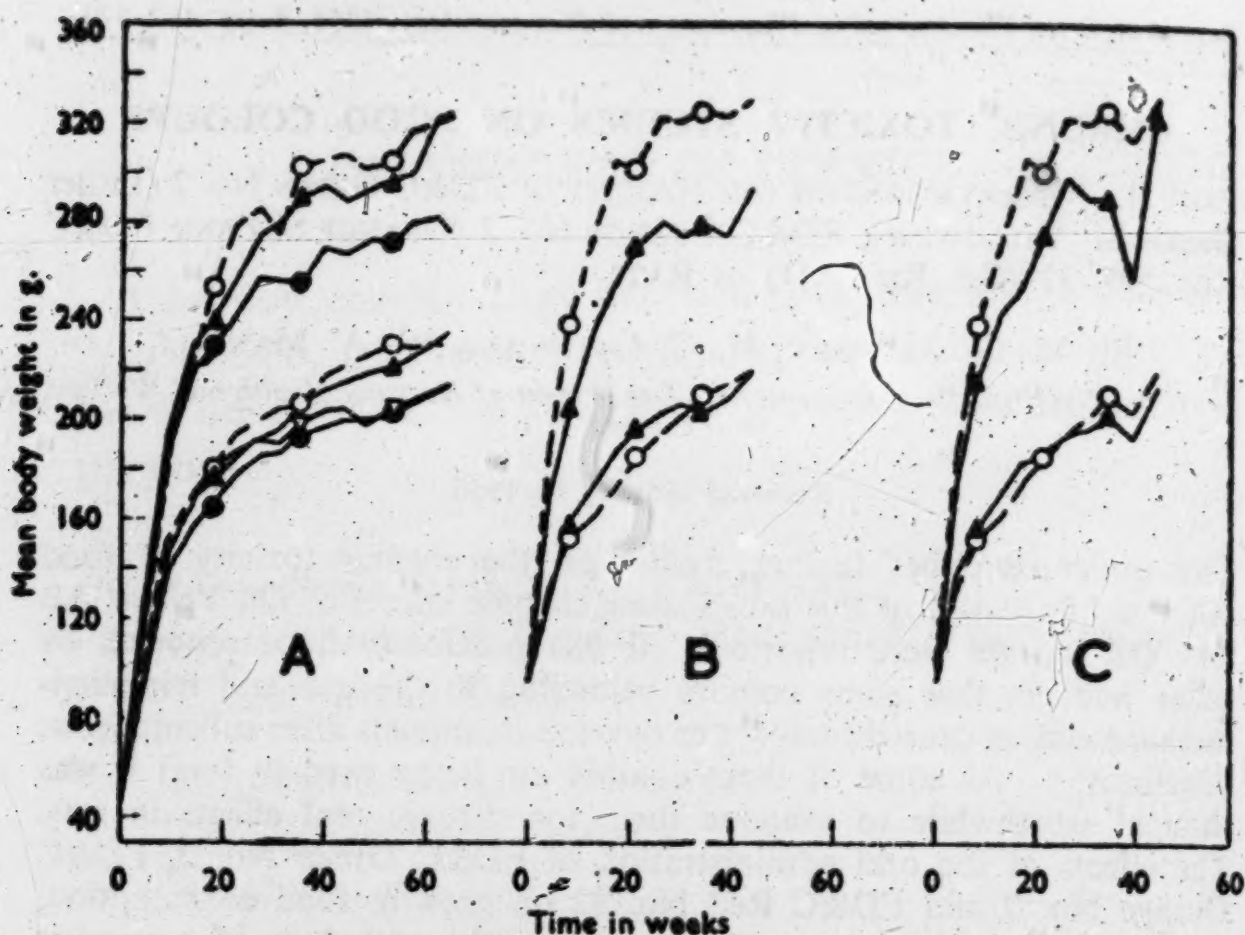


FIG. 1. Growth rate curves for control rats and those receiving the colours. Lower curves are for female rats and upper curves for male rats.

A. FD&C Green No. 2: B. FD&C Orange No. 2: FD&C Red No. 32

○ control; ▲ 0.03 per cent.; ▽ 1.5 per cent.; ● 3.0 per cent.

efficiency were not significantly affected by any of the three colours at the 0.03 per cent dietary level. However, for FD&C Red No. 32 and FD&C Orange No. 2 at the higher concentrations of 0.75 and 1.5 per cent. of the diet, growth rate, food consumption and food efficiency were noticeably affected and all rats in these two groups died before completion of the experiment. For FD&C Green No. 2, two dietary levels, 0.03 and 1.5 per cent. had no effect on growth rate, food consumption or food efficiency, but the 3.0 per cent. level noticeably affected growth rate. This may have been partly due to the amount of food consumed, which was somewhat reduced on this dietary amount. Daily doses of 200 mg./kg. and 400 mg./kg. of FD&C Red No. 32 and FD&C Orange No. 2 for 20 weeks to rats affected growth, food consumption and food efficiency, as shown in Tables I and IV.

#### *The Effect of Mortality*

At the end of the test period (65 weeks) the mortality of rats on FD&C Green No. 2 ranged from 52 to 68 per cent. for the respective groups, as shown in Table II. The control group mortality was 68 per cent. The mortality for the respective groups on dietary concentrations of FD&C Green No. 2 was not significantly different from the control. For the other two colours there was 100 per cent. mortality at the 0.75 and



# CHRONIC TOXICITY STUDIES ON FOOD COLOURS. PART II

TABLE I

SUMMARY OF DATA ON MORTALITY, FOOD CONSUMPTION AND FOOD EFFICIENCY WHEN FOOD COLOURS WERE GIVEN BY STOMACH TUBE FOR 20 WEEKS

Dose	Sex	No. rats on test	Mortality	Food consumption g./rat/day	Food efficiency g. gain/g. food consumed x 100
Control	M	10	0	13.2	5.2
	F	10	0	11.1	4.7
200 mg./kg./orally/daily FD&C Red No. 2	M	10	6	12.5	2.9
	F	10	0	12.7	3.1
200 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	13.9	3.3
	F	10	2	10.3	4.5
400 mg./kg./orally/daily FD&C Red No. 32	M	10	5	12.1	1.7
	F	10	3	10.1	1.8
400 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	10.3	1.9
	F	10	6	10.0	0.6

1.5 per cent. levels by the time the experiment was ended as shown in Table III. By the end of 20 weeks all the rats on the 1.5 per cent. level of FD&C Red No. 32 had died, and at the end of 40 weeks all the rats on the 0.75 per cent. level had died. It was not possible to make autopsies on all the animals which died during the experiment, but the tissues and organs of many of those dying on the 0.75 and 1.5 per cent. dosage were stained with the colours. The kidneys were soft, dark and swollen. The spleen was enlarged and dark in colour. The picture was one of acute toxæmia.

TABLE II  
CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test														
			1	3	5	10	15	20	25	30	35	40	45	50	55	60	65
FD&C Green No. 2																	
Control	M	25	1	6	7	8	10	11	12	13	14	14	14	14	14	16	17
	F	25	0	1	1	2	3	3	3	6	6	7	8	8	8	8	10
0.03 per cent.	M	25	0	0	0	1	1	2	4	8	8	8	8	9	11	13	14
	F	25	0	0	0	0	1	4	4	5	6	7	9	11	12	13	13
1.5 per cent.	F	25	0	0	0	0	1	1	2	2	2	3	5	7	13	13	14
3.0 per cent.	M	25	0	0	2	3	3	3	3	4	10	10	11	11	12	13	16
	F	25	0	0	0	2	2	3	4	6	8	8	9	10	10	14	14

## The Effect on Organ Weights

Organs of surviving rats were weighed at the termination of the test. The mean weights (in mg./g. of body weight) are shown in Table IV. The mean weights of a number of organs deviated significantly from those of corresponding controls. Heart, liver, spleen, kidneys and testes were the organs chiefly affected. In very few instances where increases or decreases in organ weights occurred was it possible to demonstrate pathological changes; the changes demonstrated in the testes are an exception. In a number of cases the organ weights were about the

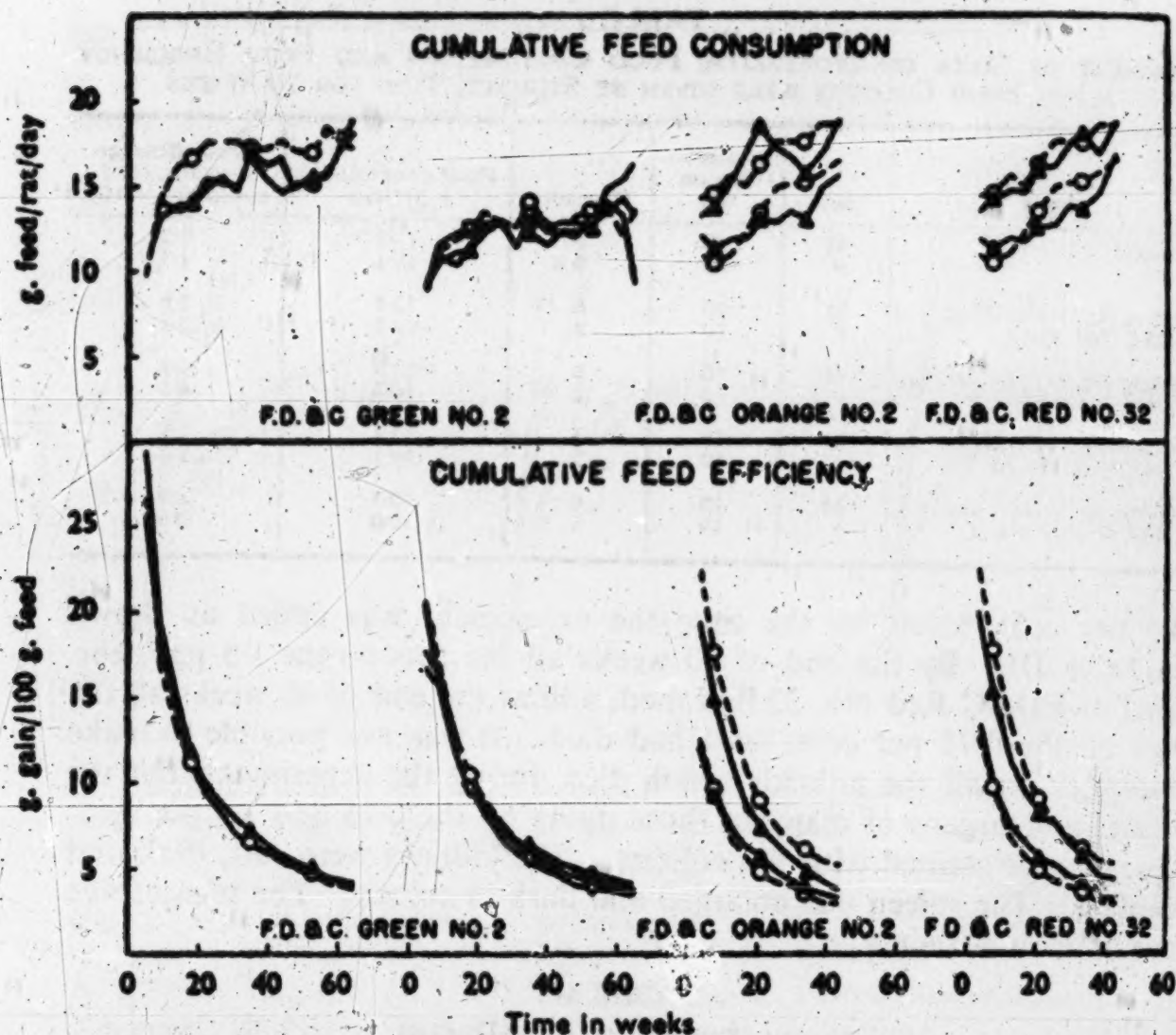


FIG. 2. Food consumption and food efficiency curves for control and test rats, male and female. For FD&C Green No. 2, values for males are shown on the left. For the other two colours, the upper curves represent male rats and the lower curves female rats.

○ Control; ▲ 0.03 per cent., ▽ 1.5 per cent., ● 3.0 per cent.

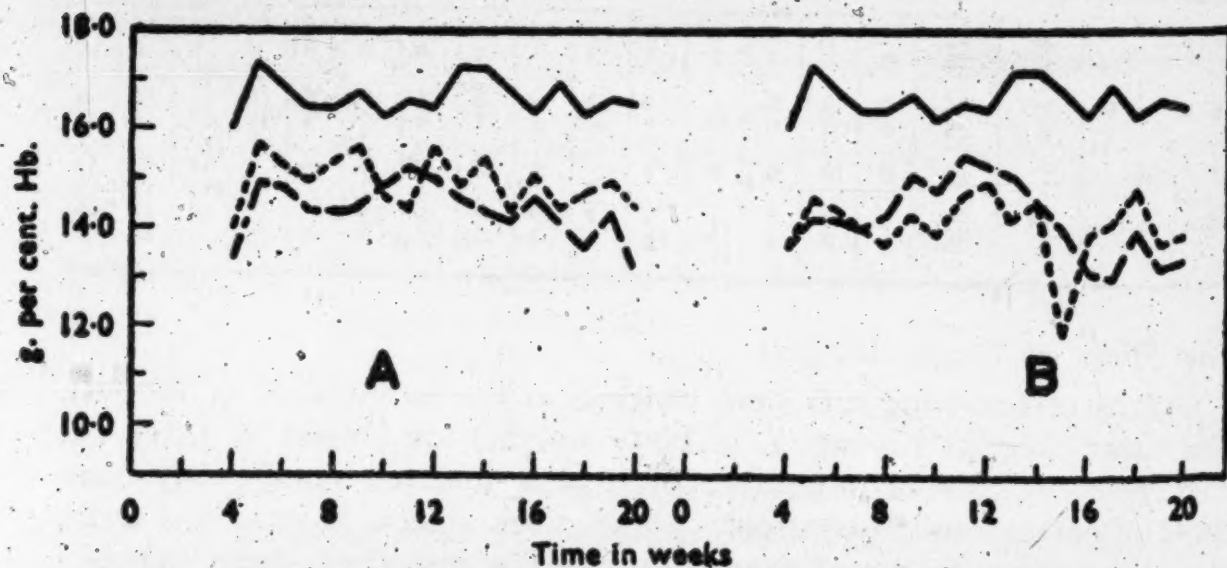


FIG. 3. Combined results of haemoglobin determinations on both sexes of control rats and those given the two colours at different doses. A. F.D.&C. Red No. 32. B. F.D.&C. Orange No. 2.

— Control; - - 200 mg./kg./rat, oral; . . . 400 mg./kg./rat oral.



## CHRONIC TOXICITY STUDIES ON FOOD COLOURS. PART II

same as the controls but the body weights of the test animals were less than the controls, suggesting the possible utilization of muscle protein. In other cases the body weights of test and control animals were about the same but the organ weights differed significantly. The changes observed in the organs in these cases appeared like compensatory changes. These results do not demonstrate a correlation of organ weight and the histopathological changes except with the testes.

TABLE III  
CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test											
			2	4	8	12	16	20	24	28	32	36	40	44
FD&C Red No. 32														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0.03 per cent.	M	20	0	0	2	3	3	7	9	9	9	9	16	18
	F	20	0	0	1	1	5	5	6	6	6	6	8	9
0.75 per cent.	M	20	2	3	4	11	15	15	15	16	17	19	20	
	F	20	0	0	0	9	11	13	15	15	15	16	20	
1.5 per cent.	M	20	2	8	11	17	19	20						
	F	20	0	2	10	18	19	20						
FD&C Orange No. 2														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0.03 per cent.	M	20	0	0	1	2	4	6	6	7	8	9	13	13
	F	20	0	0	0	0	1	2	3	4	5	6	7	7
0.75 per cent.	M	20	2	5	10	17	20							
	F	20	3	6	10	17	19	20						
1.5 per cent.	M	20	3	12	17	20								
	F	20	4	10	16	20								

### Hematology

Hæmoglobin determinations were made weekly for 20 weeks on groups of male and female rats, 10 rats to a group, given daily oral doses of 200 mg./kg. and 400 mg./kg. respectively of FD&C Red No. 32 and FD&C Orange No. 2. A slight modification of the pyridine-hæmochromogen method of Rimington was used<sup>4</sup>. The combined results of these determinations on both sexes are shown in Figure 3, and the mean values of the final determinations are shown in Table IV. The combined blood hæmoglobin values for both sexes show a significant decline in all groups on both colours. This trend was also evident from an examination of the data obtained on each sex.

Blood hæmoglobin values were also determined on the surviving rats from the other experiments. These values, also shown in Table IV, were about the same as those for the controls.

### Histopathology

A detailed examination was made of the hæmatoxylin-eosin stained paraffin sections of a number of organs including lung, heart, liver,



**TABLE IV**  
**COMPREHENSIVE SUMMARY OF OBSERVATIONS ON RATS FED FD&C RED NO. 32, FD&C ORANGE NO. 2 AND FD&C GREEN NO. 2**

Product	Dosage	No. weeks on test	No. rats surviving / No. rats on test	Mean body weight g. $\pm$ s.e.		Mean Hg (g. per cent.) $\pm$ s.e.†	Mean organ weight, mg./g. rat $\pm$ s.e.					
				Initial	Final		Heart	Liver	Kidneys	Adrenals	Spleen	Testicles
Males												
Control		44	7/20	97.7 $\pm$ 5.1	329.1 $\pm$ 26.3	15.8 $\pm$ 0.29	3.3 $\pm$ 0.08	28.6 $\pm$ 1.57	6.4 $\pm$ 0.07	0.08 $\pm$ 0.007	2.4 $\pm$ 0.13	8.8 $\pm$ 0.35
FD&C Red No. 32	0.03 per cent. of diet	44	2/20	98.4 $\pm$ 6.3	330.0 $\pm$ 6.0	16.1 $\pm$ 0.75	3.6 $\pm$ 0.05	37.0 $\pm$ 4.43	7.0 $\pm$ 1.20	0.09 $\pm$ 0.007	2.6 $\pm$ 0.15	8.9 $\pm$ 0.73
FD&C Orange No. 2	0.03 per cent. of diet	44	7/20	94.1 $\pm$ 5.8	269.4 $\pm$ 24.9	15.3 $\pm$ 0.50	3.4 $\pm$ 0.03	32.5 $\pm$ 3.31	7.2 $\pm$ 0.13	0.11 $\pm$ 0.013	2.4 $\pm$ 0.22	8.4 $\pm$ 0.63
Control		20	4/10	118.7 $\pm$ 5.7	251.0 $\pm$ 11.0	17.3 $\pm$ 0.40	3.6 $\pm$ 0.05	34.9 $\pm$ 1.55	7.6 $\pm$ 0.25	0.09 $\pm$ 0.005	2.5 $\pm$ 0.28	9.7 $\pm$ 0.38
FD&C Red No. 32	200 mg./kg./day	20	4/10	113.1 $\pm$ 4.8	155.0 $\pm$ 18.9*	14.1 $\pm$ 0.81*	4.6 $\pm$ 0.35*	38.2 $\pm$ 0.95	9.5 $\pm$ 1.55	0.15 $\pm$ 0.038*	2.9 $\pm$ 0.60	9.6 $\pm$ 1.32
FD&C Red No. 32	400 mg./kg./day	20	5/10	115.7 $\pm$ 6.4	160.2 $\pm$ 14.0*	12.8 $\pm$ 1.50*	4.7 $\pm$ 0.38*	53.1 $\pm$ 2.96*	9.6 $\pm$ 0.71*	0.13 $\pm$ 0.014*	4.5 $\pm$ 0.44*	9.6 $\pm$ 1.65
FD&C Orange No. 2	200 mg./kg./day	20	4/10	115.9 $\pm$ 4.0	200.0 $\pm$ 18.6*	14.1 $\pm$ 0.40*	4.1 $\pm$ 0.32	44.4 $\pm$ 4.46	8.8 $\pm$ 0.73	0.12 $\pm$ 0.014	4.5 $\pm$ 0.52*	11.0 $\pm$ 0.70
FD&C Orange No. 2	400 mg./kg./day	20	4/10	110.7 $\pm$ 4.0	152.8 $\pm$ 8.6*	13.8 $\pm$ 0.64*	4.2 $\pm$ 0.18*	44.8 $\pm$ 1.59*	8.9 $\pm$ 0.49	0.12 $\pm$ 0.006	5.0 $\pm$ 0.14*	12.9 $\pm$ 0.47*
Control		65	8/25	45.6 $\pm$ 2.7	323.4 $\pm$ 20.0	17.2 $\pm$ 0.35	3.2 $\pm$ 0.11	30.3 $\pm$ 1.01	6.2 $\pm$ 0.19	0.08 $\pm$ 0.008	2.7 $\pm$ 0.26	8.6 $\pm$ 0.40
FD&C Orange No. 2	0.03 per cent. of diet	65	11/25	45.5 $\pm$ 2.7	323.8 $\pm$ 10.9	16.6 $\pm$ 0.19	3.4 $\pm$ 0.07	32.6 $\pm$ 0.82	6.1 $\pm$ 0.12	0.08 $\pm$ 0.004	2.6 $\pm$ 0.11	6.5 $\pm$ 0.38
FD&C Green No. 2	3.0 per cent. of diet	65	9/25	45.4 $\pm$ 2.7	274.0 $\pm$ 12.5*	16.0 $\pm$ 0.25*	3.4 $\pm$ 0.10	34.9 $\pm$ 2.14	6.9 $\pm$ 0.38	0.09 $\pm$ 0.005	2.3 $\pm$ 0.15	5.0 $\pm$ 0.69*
Females												
Control		44	12/20	91.7 $\pm$ 3.5	219.8 $\pm$ 4.9	15.9 $\pm$ 0.22	4.1 $\pm$ 0.06	35.7 $\pm$ 0.80	7.4 $\pm$ 0.21	0.21 $\pm$ 0.007	3.4 $\pm$ 0.36	
FD&C No. 32	0.03 per cent. of diet	44	11/20	91.8 $\pm$ 2.7	214.1 $\pm$ 2.9	14.9 $\pm$ 0.66	4.2 $\pm$ 0.15	39.2 $\pm$ 1.38*	8.1 $\pm$ 0.27	0.23 $\pm$ 0.010	3.9 $\pm$ 0.64	
FD&C Orange No. 2	0.03 per cent. of diet	44	11/20	95.1 $\pm$ 3.4	219.4 $\pm$ 5.8	15.6 $\pm$ 0.22	4.2 $\pm$ 0.13	37.8 $\pm$ 1.36	7.8 $\pm$ 0.18	0.24 $\pm$ 0.011	3.6 $\pm$ 0.15	
Control		20	9/10	93.0 $\pm$ 3.9	166.9 $\pm$ 6.5	15.7 $\pm$ 0.65	4.5 $\pm$ 0.41	37.5 $\pm$ 1.38	8.2 $\pm$ 0.45	0.26 $\pm$ 0.031	3.1 $\pm$ 0.33	
FD&C Red No. 32	200 mg./kg./day	20	10/10	92.3 $\pm$ 4.0	147.6 $\pm$ 5.8*	14.7 $\pm$ 0.23	4.5 $\pm$ 0.18	43.0 $\pm$ 1.73	8.7 $\pm$ 0.34	0.20 $\pm$ 0.004	4.3 $\pm$ 0.15*	
FD&C Red No. 32	400 mg./kg./day	20	7/10	91.6 $\pm$ 3.5	124.9 $\pm$ 4.6*	13.4 $\pm$ 0.45*	5.0 $\pm$ 0.18	51.8 $\pm$ 1.92*	9.6 $\pm$ 0.14	0.16 $\pm$ 0.007*	6.5 $\pm$ 2.05	
FD&C Orange No. 2	200 mg./kg./day	20	8/10	88.8 $\pm$ 3.3	153.6 $\pm$ 3.1	13.7 $\pm$ 0.19*	4.3 $\pm$ 0.07	40.2 $\pm$ 1.34	7.8 $\pm$ 0.30	0.17 $\pm$ 0.011	5.6 $\pm$ 0.27*	
FD&C Orange No. 2	400 mg./kg./day	20	4/10	89.9 $\pm$ 4.0	102.8 $\pm$ 11.2*	12.9 $\pm$ 1.37*	5.0 $\pm$ 0.31	55.1 $\pm$ 5.14*	9.9 $\pm$ 0.43	0.20 $\pm$ 0.022	5.3 $\pm$ 0.73*	
Control		65	15/25	39.6 $\pm$ 2.4	227.9 $\pm$ 3.9	16.0 $\pm$ 0.19	4.1 $\pm$ 0.07	35.4 $\pm$ 0.84	7.0 $\pm$ 0.18	0.22 $\pm$ 0.008	3.6 $\pm$ 0.13	
FD&C Green No. 2	0.03 per cent. of diet	65	11/25	39.4 $\pm$ 2.4	236.7 $\pm$ 6.9	16.4 $\pm$ 0.30	3.9 $\pm$ 0.09	31.9 $\pm$ 1.05*	6.6 $\pm$ 0.21	0.21 $\pm$ 0.011	3.2 $\pm$ 0.06*	
FD&C Green No. 2	1.5 per cent. of diet	65	11/25	39.6 $\pm$ 2.3	213.6 $\pm$ 8.7	16.1 $\pm$ 0.33	3.6 $\pm$ 0.06*	24.4 $\pm$ 0.39*	6.1 $\pm$ 0.13*	0.16 $\pm$ 0.017*	2.7 $\pm$ 0.20*	
FD&C Green No. 2	3.0 per cent. of diet	65	11/25	39.7 $\pm$ 2.4	210.6 $\pm$ 7.3*	16.0 $\pm$ 0.21	4.3 $\pm$ 0.12	34.9 $\pm$ 1.16	7.3 $\pm$ 0.17	0.19 $\pm$ 0.005*	3.6 $\pm$ 0.22	

\* significant at P = 0.05

† determination on 5 rats



**TABLE V**  
**SUMMARY OF HISTOPATHOLOGICAL FINDINGS**

	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32
Sex ..	Male					Female					Female	Male	Female	Male			Female			Male			Female					
Dose ..	0.03 per cent. in diet					0.03 per cent. in diet					1.5 per cent. in diet	3.0 per cent. in diet	3.0 per cent. in diet	200 mg./kg./day			200 mg./kg./day			400 mg./kg./day			400 mg./kg./day					
Number of rats on test ..	25	20	25	20	20	25	20	25	20	20	25	25	25	25	25	25	25	10	10	10	10	10	10	10	10	10	10	
Number of survivors ..	8	7	11	7	2	15	7	12	13	11	15	11	8	9	15	11	4	4	4	5	9	8	10	4	4	4	4	
Number of rats examined ..	5	5	6	7	2	4	7	6	11	10	4	6	5	8	4	6	4	4	4	6	8	10	4	4	4	3	6	
Duration of test-weeks ..	65	44	65	44	44	65	44	65	44	44	65	65	65	65	65	65	20	20	20	20	20	20	20	20	20	20	20	
Bladder parasites ..			3	4	1	1		2	1	1						2					1							
Hydronephrosis ..																												
Chronic glomerulonephritis ..								1	1	1																		
Pyelonephritis ..																												
Interstitial nephritis ..																												
Altered spermatogenesis ..				1										7										1	3			1
Necrotic casts in testes tubules ..														6														
Ovary fibroma ..																												
Ovary cystadenoma ..									1																			
Perioophoritis ..																1												
Liver necrosis ..														1														
Lung papilloma ..																												
Purulent pericarditis ..																										1		
Laryngeal abscess ..																												
Acute tracheitis ..																											1	

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spleen, thyroid, pancreas, stomach, small intestine, kidney, urinary bladder, adrenal, testes, ovaries and thymus. A summary of the findings is given in Table V. There were no consistent histopathological changes observed in the tissues or organs studied that could be attributed to the toxic effects of the colours with the possible exception of testicular change which was observed in animals on the higher dietary concentrations. These findings were particularly noticeable in rats on dietary levels of 3.0 per cent. FD&C Green No. 2 and in those receiving daily oral dosage of 400 mg./kg. of FD&C Red No. 32. On the 3.0 per cent. level of the green colour testicular change was a constant finding. In seven out of eight animals there was tubular atrophy and incomplete spermatogenesis. The change, although constant, was variable in degree. In some testes a few tubules showed complete absence of spermatogenic cells and in others the spermatogenic cells were greatly reduced. Several tubules in each testis contained deep-blue-staining caseous necrotic casts. Remnants of sperm were present in the necrotic debris. The spermatogenic cells and the supporting network of the tubules were undergoing varying degrees of degenerative changes. In some tubules it was apparent that the necrotic casts were being formed from the degenerating cells.

**SUMMARY**

1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2 in concentrations of 0.03 per cent. in the diet did not affect growth, food consumption or food efficiency in either male or female rats.

2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 and 1.5 per cent. in the diet, there was 100 per cent. mortality before the completion of the experiment.

3. FD&C Green No. 2 in a concentration of 3.0 per cent. in the diet adversely affected the growth rate which may have been due in part to the amount of food consumed. At the 1.5 per cent. concentration in the diet of female rats no effect on growth rate, food consumption or food efficiency was observed.

4. Haemoglobin production was not affected by 0.03 per cent. in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg./kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks. Haemoglobin values were not affected by any of the dosage levels of FD&C Green No. 2.

5. The only significant pathology was found in the testes of those rats receiving a dietary level of 3.0 per cent. of FD&C Green No. 2, or an oral dosage of 400 mg./kg. of FD&C Red No. 32.

The authors wish to acknowledge the technical assistance of Miss Elizabeth Carmichael, Miss Elaine Connell and Miss Rita Carioto.

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**Federal Security Agency**  
**FOOD AND DRUG ADMINISTRATION**  
**SERVICE AND REGULATORY ANNOUNCEMENTS**  
Food, Drug, and Cosmetic No. 3

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**COAL-TAR COLOR REGULATIONS**

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**INTRODUCTION**

This publication contains the text of the regulations, promulgated under authority of the Federal Food, Drug, and Cosmetic Act of 1938, for the listing of coal-tar colors which are harmless and suitable for use in food, drugs, and cosmetics, and certification of batches of such colors.

Included are lists of coal-tar colors for use in food, drugs, and cosmetics; in drugs and cosmetics and externally applied drugs and cosmetics, as well as specifications for the identity and purity to which these colors must conform in order to be certified.

This publication also contains regulations covering certification of mixtures of certified colors with or without harmless diluents, fees for the certification service, and other information pertinent to carrying out a system of certification as provided by sections 406 (b), 504, 604, and 706 of the Act. (Emphasis Supplied).

Paul V. McNutt, Administrator,  
Washington, D. C., August 27, 1940.

\* \* \*

**GENERAL SPECIFICATIONS FOR STRAIGHT  
COLORS (p. 3).**

\* \* \*

Section 135.02 *General specification for straight Colors.*

No batch of a straight color listed in section 135.03, 135.04, or 135.05 shall be certified under these regulations unless—

(a) It is free from all impurities, (other than those named in paragraph (b) or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 percent.

Arsenic (as  $\text{As}_2\text{O}_3$ ), not more than 0.00014 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in section 135.04 or 135.05—

Lead (as Pb), not more than 0.002 percent.

Arsenic (as  $\text{As}_2\text{O}_3$ ), not more than 0.0002 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in section 135.04 or 135.05.

Soluble barium (in dilute HCl) (as  $\text{BaCl}_2$ ), not more than 0.05 percent.

### **STRAIGHT COLORS — FOODS, DRUGS AND COSMETICS**

Section 135.03 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.*

(a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these



regulations, for use in food (subject to the restrictions prescribed by subsection (c) hereof), drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specification herein set forth for such color.

\* \* \*

**FD&C Orange No. 1 (p. 5)**

**SPECIFICATIONS**

Monosodium salt of 4-p-sulfophenylazo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.  
alpha-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Orange No. 1 (p. 5).**

**SPECIFICATIONS**

1-o-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

o-Toluidine, not more than 0.05 percent.

beta-Naphthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

## **FD&C Red No. 32 (p. 6).**

### **SPECIFICATIONS**

**1-Xylylazo-2-naphthol.**

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Xylidine, not more than 0.1 percent.

beta-Naphthol, not more than 0.05 percent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 97.0 percent.

Boiling range of xylidine, obtained by reduction of the dye, 95 percent between 212-232° C.

\* \* \*

## **FD&C Yellow No. 1 (p. 7)**

### **SPECIFICATIONS**

Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride) not less than 85.0 percent.



## **FD&C Yellow No. 2**

### **SPECIFICATIONS**

Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

## **FD&C Yellow No. 3**

### **SPECIFICATIONS**

1-Phenylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 99° C.

## **FD&C Yellow No. 4**

### **SPECIFICATIONS**

1-o-Tolylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 120° C.

\* \* \*

### **LAKES (p. 8)**

Any lake made by extending on a substratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this subsection by combining such color with the basic radicle aluminum or calcium.

#### **SPECIFICATIONS**

Ether extracts, not more than 0.3 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble in HCl, not more than 0.5 percent.

Intermediates, not more than 0.1 percent.

(b) Each lake made as prescribed under the caption "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, the listed name of the color from which the lake is prepared;

Second, the name of the basic radicle combined in such color; and

Third, the word "Lake."

(For example, the name of a lake prepared by ex-

tending the aluminum salt prepared from FD&C Orange No. 1 upon the substratum would be FD&C Orange No. 1—Aluminum Lake.)

(c) No lake listed in subsection (a) shall be certified for any use in food except external application to shell eggs.

\* \* \*

### **MIXTURES WHICH MAY BE CERTIFIED (p. 35)**

Section 135.06 *Mixtures which may be certified.*

(a) A batch of a mixture which contains no straight color listed in section 135.04 or 135.05 may be certified, in accordance with the provisions of these regulations, for use in food (subject to the restrictions prescribed in subsection (d) hereof), drugs, and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatsoever since such previous certification, except by mixing into such batch of mixture;

(2) each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) no diluent (except resins, natural gum, pectin and in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a non-nutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with section 135.08 (c), and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

\* \* \*

(d) No mixture which contains a lake listed in sec-



tion 135.03 shall be certified for any use in food except external application to shell eggs. (Emphasis supplied).

### **CERTIFICATION (p. 38).**

#### **Section 135.09** *Certification.*

(a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary that—

(1) A request submitted in accordance with section 135.08 appears to contain no untrue statement of a material fact;

(2) in the case of a stright color, such color conforms to the specifications set forth therefor in sections 135.02, 135.03, 135.04, and 135.05;

(3) in the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein; and

(4) the batch covered by such request otherwise appear to comply with these regulations, the Food and Drug Administration shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by section 135.10, is a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be.

\* \* \*

### **LIMITATIONS OF CERTIFICATES (p. 39).**

#### **Section 135.10** *Limitations of certificates.*

\* \* \*

(i) If a coal-tar color from a batch containing any lake listed in section 135.03 is used in coloring any food except shell eggs, such color so used shall be con-



sidered to be from a batch that has not been certified in accordance with these regulations.

### **LABELING (p. 40)**

#### **Section 135.11 *Labeling.***

(a) The label on each package of coal-tar color from a batch that has been certified in accordance with these regulations shall bear, in addition to other words, statements, and information required by or under authority of the Act to appear on such label—

\* \* \*

(4) in case such batch was certified for use only in drugs and cosmetics, the statement "*Not for use in coloring food*"; or in case such batch was certified for use only in externally applied drugs and cosmetics, the statement "*Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucous membrane*"; or in case such batch is a mixture containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture, the statement "*Not for use in coloring any food except*-----" (the blank to be filled in by the name of such food); or in case such batch contains any lake listed in section 135.03 or any diluent permitted by clause (3) of section 135.06 (a) only because such batch is for use in coloring shell eggs, the statement "*Not for use in coloring any food except shell eggs.*"

### **PROCEDURE FOR ADMITTING COLORS TO LISTING (p. 42)**

#### **Section 135.14 *Procedure for admitting colors to listing.***

(a) An application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05 shall be accompanied by—

(1) full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) a full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) a full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) a full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) a full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) a five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) the advance deposit prescribed by section 135.15 (b) (2).

(b) If the Administrator determines, after such investigation as he considers to be necessary, that—

(1) such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;



(2) practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) practical and accurate methods exist for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith,

the Administrator, for the purpose of listing such color in section 135.03, 135.04, or 135.05, shall proceed with a proposed amendment to these regulations as prescribed by section 701 (e) of the Act.

(c) If the Administrator, after such investigation as he considers to be necessary, determines that such color does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in section 135.03, 135.04, or 135.05, the Administrator shall give notice thereof to the applicant, stating the respects in which such color does not so comply.

**FEES (p. 43).**

\* \* \*

(b) (1) The fee for the service provided by these regulations, in the case of each application for the admission of a coal-tar color listing in section 135.03, 135.04 or 135.05, shall be the cost incurred by the Agency in making the investigations contemplated by section 135.14 (b) and (c).

(2) Such application shall be accompanied by an advance deposit of \$500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrears in the payment of such fee. Any ex-

cess advance deposit so made shall be returned to the applicant after the close of such investigation.

## APPENDIX (p. 44)

### List of Colors

#### LIST OF COLOR NAMES SPECIFIED IN THE REGULATIONS AND FORMER NAMES OF SUCH COLORS

*Group I.*—Certifiable For Use in Food, Drugs and Cosmetics:

<i>Listed as</i>	<i>Formerly known as</i>
FD&C Blue No. 1	Brilliant Blue FCF.
FD&C Blue No. 2	Indigotine.
FD&C Green No. 1	Guinea Green B.
FD&C Green No. 2	Light Green SF Yellowish.
FD&C Green No. 3	Fast Green FCF.
FD&C Orange No. 1	Orange I.
FD&C Orange No. 2	Orange SS.
FD&C Red No. 1	Ponceau 3R.
FD&C Red No. 2	Amaranth.
FD&C Red No. 3	Erythrosine.
FD&C Red No. 4	Ponceau SX.
FD&C Red. No. 32	Oil Red XO.
FD&C Yellow No. 1	Naphthol Yellow S.
FD&C Yellow No. 2	Naphthol Yellow S—Potassium salt.
FD&C Yellow No. 3	Yellow AB.
FD&C Yellow No. 4	Yellow OB.
FD&C Yellow No. 5	Tartrazine.
FD&C Yellow No. 6	Sunset Yellow FCF.

#### GENERAL LABELING REQUIREMENTS FOR COAL-TAR COLORS (p. 53).

The labeling requirements for coal-tar colors are found in part in the Food, Drug, and Cosmetic Act itself and in part in the coal-tar color regulations. The label should contain.

\* \* \*

- (7) In the case of a color certified only for a limited use, a statement setting forth this limitation. (Color Regulations: Sec. 135.11 (a) (4) .).



**U. S. DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE**

**Food and Drug Administration**

**Washington 25, D. C.**

**FOR RELEASE**

**Wednesday, November 16, 1955**

**HEW-C81**

The Food and Drug Administration today removed three widely used coal-tar dyes from the list of approved coloring materials which may be added to foods.

The order, effective immediately, was signed by Secretary of Health, Education, and Welfare Marion B. Folsom under the Food, Drug, and Cosmetic Act. The law requires that food colors be certified as completely harmless.

FDA Commissioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods, but recent scientific investigation shows they are not harmless when fed in large amounts.

The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, especially hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges.

While manufacturers will no longer label and sell

these three colors for food use they may label and sell them for external drug and cosmetic use. In the future the colors will be identified as Ext. D&C Orange No. 3, Ext. D&C Orange No. 4, and Ext. D&C Red No. 14. The order announcing the change is the final version of a regulation based on evidence received at a hearing held in December 1953.

For many years the certification of coal-tar colors was carried on as a voluntary arrangement between the industry and the Government. Certification became mandatory when the Food, Drug, and Cosmetic Act of 1938 was passed. Under the law manufacturers of coal-tar colors routinely submit a sample from each batch to the Food and Drug Administration laboratories in Washington for testing to determine whether they meet required standards of purity. The law requires all coal-tar food colors to be "harmless and suitable for use in food."

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U. S. DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Washington 25, D. C.

CORRECTION

Please correct Release HEW-C81, dated November 16, 1955. Make second paragraph read as follows:

"The order is effective 90 days after publication in the Federal Register of November 16, 1955. It was signed by Secretary of Health, Education, and Welfare Marion B. Folsom under the Food, Drug, and Cosmetic Act. The law requires that food colors be certified as completely harmless."